THE EFFECT OF GAIT RETRAINING ON EXTERNAL LOADING AND ASSOCIATED BONY LOADING IN RUNNERS

by

Rebecca Elizabeth Fellin

A dissertation submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Biomechanics and Movement Science

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ABSTRACT

In the United States alone, approximately 16.4 million people participate in running activities. Unfortunately, up to 79% of these runners are injured each year. One more serious type of injury runners sustain is a tibial stress fracture, which is an injury that requires 6-8 weeks of rest. These injuries also have an alarmingly high 36% re-injury rate. Excessive vertical loading, such as load rates and tibial shock, has been linked to an increased risk of tibial stress fractures. Many runners exhibit excessive vertical loading bilaterally. Furthermore, torsional loading, quantified by the free moment, has been also implicated in tibial stress fracture development. Although both of these risk factors involve external loading, stress fractures occur due to loading at the bony level. Gait retraining to decrease vertical loading has been effective at decreasing these loads on the trained limb that received feedback. However, the impact of gait retraining on other risk factors such as free moment, contralateral limb loading, and the bony loading along the entire region where stress fractures are most common is unknown. Therefore, this dissertation consisted of three aims to examine changes following gait retraining with respect to each of these areas.

The purpose of Aim 1 was to identify if runners who have high vertical and torsional loads can decrease those torsional loads through gait retraining to decrease vertical loading. We hypothesized that runners would decrease those loads following gait retraining. We further hypothesized that

the decrease in torsional loading would be less than the decrease in vertical loading as the subjects were not receiving feedback on torsional loads. We collected data on twenty runners both pre and post gait retraining during overground running at 3.7 m/s. The gait retraining protocol consisted of eight sessions of real-time visual feedback during treadmill running at a self-selected speed. This feedback was from an accelerometer attached to the anterior-medial aspect of the subject's tibia on their limb with higher loads. The results revealed that runners with high peak adduction free moments reduce this peak following gait retraining. The decrease in free moment was moderately correlated to the decrease in vertical loading. Furthermore, the subjects decreased their free moment to a lesser degree than their vertical loading.

The purpose of Aim 2 was to identify if reductions in vertical loading on the trained limb transfer to the contralateral, untrained limb. We hypothesized that runners would decrease vertical load rates and tibial shock on their trained and untrained, contralateral limb following gait retraining. We collected data on ten runners both pre and post gait retraining during treadmill running at 3.35 m/s and a self-selected speed. The gait retraining protocol consisted of eight sessions of real-time visual feedback during treadmill running at a self-selected speed. This feedback was from an accelerometer attached to the anterior-medial aspect of the subject's tibia on their limb with higher loads. Runners significantly decreased vertical load rates and tibial shock following gait retraining on both limbs and both running speeds.

The purpose of Aim 3 was to identify if runners with high vertical loading decrease tibial strain rates from the midshaft to distal third following gait retraining. We hypothesized that runners would decrease tibial strain rates following gait retraining. Furthermore, we hypothesized that these tibial strain rate decreases would be proportional to the subject's external, vertical loading decreases. We collected data on five runners both pre and post gait retraining during overground running at 3.7 m/s. The gait retraining protocol consisted of eight sessions of real-time visual feedback during treadmill running at a self-selected speed. This feedback was from an accelerometer attached to the anterior-medial aspect of the subject's tibia on their limb with higher loads. The results were mixed as only 4/5 subjects demonstrated decreased tibial strain rates following gait retraining. These external loading decreases were similar in magnitude to the strain rate decreases for 2/5 subjects. Additional subjects should be studied to further validate these findings.

Chapter 1

INTRODUCTION

Regular exercise is important to maintain a healthy lifestyle and to reduce one's risk for cardiovascular problems, obesity, as well as many other chronic diseases (Estok and Rudy 1987; Koplan, Rothenberg et al. 1995). The American College of Sports Medicine began their 'Exercise is Medicine' initiative to promote exercise as an adjunct prescription for most medical conditions. Their initiatives include encouraging five days of moderate to vigorous physical activity per week. Running is a convenient exercise for many people because it can be done anywhere, is low cost, and does not require any specialized equipment. As a result, approximately 16.4 million Americans are engaged in the sport of running today (SGMA 2009).

Unfortunately, it has been reported that up to 79% of runners sustain an injury in a given year (van Gent, Siem et al. 2007). Stress fractures are one of the most common injuries, with a 4-22% annual incidence reported in runners (Bennell, Malcolm et al. 1996; Arendt, Agel et al. 2003). Stress fractures occur most frequently in the tibia (Taunton, Ryan et al. 2002). Recovery typically requires refraining from running and other weight bearing exercises for four to eight weeks (Brukner, Bradshaw et al. 1998) followed by a gradual resumption of training. The recovery time and rehabilitative training time averages to nineteen weeks of lost training (Ross and Allsopp 2002).

This lengthy time away from exercise can be detrimental to one's physical health. Additionally, there is an alarmingly high, 36% rate of re-injury (Hauret, Shippey et al. 2001).

Stress fractures are believed to be caused repetitive loading on bone with each repetition of loading being less than the ultimate stress of bone. Repetitive loading, such as running, marching and other vigorous activities can cause microdamage, sub-millimeter cracks, to bone. Typically, bone can repair this microdamage through the bone remodeling process, which includes removing the damaged bone and replacing it with new bone. In tis processing, basic multicellular units (BMUs) identify bone that needs repair. The BMUs create osteoclasts to absorb bone, and then osteoblasts form new bone to replace the bone absorbed (Frost 2001). However, the microdamage from repetitive loading can accumulate if the bone remodeling process is disrupted or overwhelmed by the amount of damage (Pepper, Akuthota et al. 2006). This accumulation of microdamage through repetitive loading can result in these cracks propagating and a stress fracture or a complete fracture (Frost 1997; Pepper, Akuthota et al. 2006).

There are many risk factors for sustaining a stress fracture including structure, nutrition, physiology and training. However, most researchers and clinicians agree that biomechanics play an important role in the development of this injury. Researchers have recently focused on loading variables during early stance. A recent meta-analysis of these studies indicates that these loading variables, such as loading rates of the vertical ground reaction force as well as tibial shock, most often differentiate between injured and healthy cohorts (Zadpoor and Nikooyan 2011).

Free Moment and Gait Retraining

In addition to vertical loading, the tibia is simultaneously exposed to bending, shear and torsional loads with each footstrike (Ekenman, Halvorsen et al. 1998). Excessive torsional loading, specifically the free moment, has also been implicated in tibial stress fracture (TSF) incidence (Milner, Davis et al. 2006; Pohl, Mullineaux et al. 2008). Free moment is defined as the rotational force about a vertical axis caused by frictional forces between the shoe and the ground (Holden and Cavanagh 1991).

We have demonstrated that runners can reduce their vertical loads through real-time feedback in a single session (Crowell, Milner et al. 2010). We have also shown that runners with excessive vertical loads can be trained to consistently reduce their tibial shock (TS) and vertical average load rate (VALR) through a gait retraining protocol. In addition, these changes have persisted for up to 6 months (Davis, Crowell, et al. 2009). The protocol consisted of eight sessions of gait retraining using real-time visual feedback of their TS and verbal instruction to 'run softer'. The protocol used a faded feedback design to facilitate internalization and persistence of their new gait pattern (Winstein 1991). These long-term gait changes are promising as it appears runners may be able to maintain their new running gait pattern months after feedback has been removed. This modification suggests that runners were successfully able to internalize cues needed for their new running gait pattern.

Although this retraining program has been effective at decreasing vertical loading, it may also be important to reduce torsional loading as well. A preliminary study indicated that runners with high vertical loading frequently had associated high torsional loading as well (Fellin and Davis 2009). We undertook a preliminary study to examine if the gait retraining protocol, designed to decrease vertical loading, also reduced torsional loading. The results indicated that some of these subjects were able decrease their excessive torsional loading despite only receiving feedback to decrease vertical loading. While these preliminary results are promising, further study of more runners is necessary to further validate these results. Lowering excessive torsional, as well as vertical loading, should help to further reduce injury risk in these runners.

Untrained Limb Effects of Gait Retraining

Runners often exhibit high loading bilaterally (Zifchock, Davis et al. 2006). However, it is difficult for the subject to concentrate on retraining of both limbs at the same time. Therefore, our gait retraining studies have addressed training the limb with the highest impact loading, without attention to the untrained limb. As the regulation of human locomotion requires interlimb coordination (Dietz 1992; Dietz 2002; Dietz, Muller et al. 2002), it is possible there may be cross transfer effects to the untrained limb. Multiple unilateral training protocols have reported cross transfer effects to the untrained limb (Ting, Kautz et al. 2000; Dietz, Muller et al. 2002; Lee, Gandevia et al. 2009; Savin, Tseng et al. 2010). A study that applied a perturbation to one leg resulted in bilateral step length changes during and after the perturbation (Savin, Tseng et al. 2010). A recent study (Lee, Gandevia et al. 2009) reported that strength training of one limb resulted in increased strength of the untrained limb. However, the strength gains in the untrained limb were less than that found for the trained limb. Dietz and colleagues found that unilateral stepping movements produced bilateral lower limb muscle activity (Dietz, Muller et al. 2002). Furthermore, Ting and colleagues studied healthy subjects performing unilateral cycling and found these subjects exhibited similar muscle activity between the pedaling and non-pedaling limbs (Ting, Kautz et al. 2000).

Therefore, it is possible that the changes in mechanics observed in the retrained limb transfer to the contralateral, untrained limb. Preliminary data suggest that there may be a crossover effect of this gait retraining protocol (Fellin and Davis 2010). If these results are further validated with additional subjects, retraining on one limb may be able to reduce the risk for injury bilaterally.

Tibia Model

Measurement of external loads modified by gait retraining does not provide direct indication of the loads that the tibia experiences. It is possible to directly measure loads, such as tibial strains with a strain gauge. However, these devices have to be attached directly to the bone. Therefore, the process is invasive, can be painful, and the strain gauges may influence the subject's motion. A non-invasive alternative is to use a model of the tibia to estimate these bony loads.

The earliest models of the tibia were two-dimensional. Scott and Winter designed a tibial model to analyze the loading of the distal third of the lower leg during running (Scott and Winter 1990). The authors concluded that the plantarflexors protect the tibia by counteracting bending and shear forces caused by the ground reaction force during running. In another study, Sasimontonkul and colleagues used a two-dimensional model of the lower limb to calculate bone contact forces during running (Sasimontonkul, Bay et al. 2007). They found that the muscle forces magnified the compressive forces produced by the ground reaction force. Additionally, the muscle forces provided a protective effect by inducing shear in the opposite direction of the ground reaction force produced shear. Although results of these two dimensional methods were useful, they provided an incomplete description of the loading of the tibia during running.

There have been several three-dimensional studies of tibial loading in running. The earliest study combined subject specific geometry, obtained from magnetic resonance imaging (MRI) with ground reaction force data (van den Bogert and Nigg 1993). These authors observed a peak in stress around the vertical impact peak in early stance. They also found that the anterior tibia was in tension and the posterior was in compression for the majority of stance. DeWoody and associates used a forward dynamics approach and found that tibial stresses were underestimated by one order of magnitude if muscle forces were omitted (DeWoody, Martin et al. 2001). Furthermore, they found that the peak stresses occurred in early stance, before the peak ground reaction force. Crowell examined peak tibial strain rates in running using a static optimization method combined with a simple beam model (Crowell 2009). He found that following a gait retraining program the peak strain rates, which occurred in early stance, decreased (Crowell 2009). Consistent with van den Bogert and Nigg he also found that the tibia was in tension on the anterior side and compression on the posterior side (van den Bogert and Nigg 1993). Two additional studies by Edwards and colleagues examined tibial loads at the peak ground reaction force (Edwards, Taylor et al. 2009; Edwards, Taylor et al. 2010). These authors also found that the tibia was in tension on the anterior side and compression on the posterior side, which is consistent with strain gauge data (Burr, Milgrom et al. 1996). However none of these models examined the entire region of the midshaft to distal third during the initial loading phase of running.

Summary

In summary, increased vertical and torsional loads are associated with tibial stress fractures. Furthermore, these factors can occur bilaterally, placing both of the runner's limbs at higher risk for injury. Gait retraining has been shown to decrease excessive vertical loads that are associated with injury. This research aims to determine whether subjects completing gait retraining: 1) reduce torsional loads on their trained leg following gait retraining, 2) transfer reductions in vertical loads to the untrained leg and 3) transfer these vertical load decreases to the bony level.

Specific Aims and Hypotheses

Aim 1: To determine if runners are able to decrease torsional loads following gait retraining to decrease vertical loads.

Hypothesis 1.1: Runners will significantly reduce peak adduction free moment following gait retraining.

Hypothesis 1.2: These decreases in free moment will be correlated with the vertical load decreases.

Aim 2: To determine if there is any cross-over effect of the retraining to the untrained, contralateral limb.

Hypothesis 2.1: Following gait retraining, tibial shock will decrease in the untrained limb, but to a lesser degree than the trained limb.

Hypothesis 2.2: Following gait retraining, vertical average and instantaneous loading rates will decrease in the untrained limb, but to a lesser degree than the trained limb.

Aim 3: To determine if changes in external lower extremity loads are associated with strain rates on the tibia following gait retraining.

Hypothesis 3.1: Tibial strain rates during initial loading will decrease between the midshaft and distal third, following gait retraining.

Hypothesis 3.2: Tibial strain rates will decrease proportionately to the subject's decrease in external vertical loading

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Chapter 2

EFFECT OF GAIT RETRAINING ON FREE MOMENT DURING RUNNING

Abstract

Tibial stress fractures are a serious running injury that often requires 2 months off from running. Both high vertical loading rates and torsional loading (free moment adduction peak) have been implicated in tibial stress fractures. Gait retraining with real-time visual feedback has been effective to decrease vertical loading. However, cross transfer from vertical to torsional loading had not been examined. The purpose of this study was to examine the effect of a gait retraining protocol on free moment. We hypothesized that runners would decrease their free moment adduction peak following gait retraining. **Methods**: Twenty runners with high vertical loads underwent an eight session gait retraining protocol with real-time visual feedback. Vertical load rates and free moment adduction peak were measured pre and post gait retraining during overground running at 3.7 m/s. **Results**: Following gait retraining, there was a trend towards a decrease in free moment adduction peak (p=0.068). However, runners with high peak adduction free moment pre gait retraining (n=10) significantly decreased these loads following gait retraining. In this sub-group, correlations between vertical loading decreases and free moment adduction peak were moderate (665-.710) and statistically significant. **Conclusion**: Overall, there was a trend

towards a decrease in torsional loading following gait retraining. In the sub-group of subjects with excessive torsional loads pre-gait retraining these torsional loads were significantly decreased following gait retraining aimed at decreasing vertical loads. The decrease in torsional loads was significantly related to the decrease in vertical loads following gait retraining. Torsional loads were decreased to a smaller magnitude than vertical loads following gait retraining.

Introduction

Regular exercise is important to maintain a healthy lifestyle and to reduce one's risk for cardiovascular problems, obesity, as well as many other chronic diseases (Estok and Rudy 1987; Koplan, Rothenberg et al. 1995). Running is a convenient exercise for many people because it can be done anywhere, is low cost, and does not require any specialized equipment. As a result, approximately 16.4 million Americans are engaged in the sport of running today (SGMA).

Unfortunately, it has been reported that up to 79% of runners sustain an injury in a given year (van Gent, Siem et al. 2007). Stress fractures are one of the most common injuries, with a 4-22% annual incidence reported in runners (Bennell, Malcolm et al. 1996; Arendt, Agel et al. 2003). Stress fractures occur most frequently in the tibia (Taunton, Ryan et al. 2002). Recovery typically requires refraining from running and other weight bearing exercises for four to eight weeks (Brukner, Bradshaw et al. 1998) followed by a gradual resumption of training. The recovery time and rehabilitative training time averages to nineteen weeks of lost training (Ross and Allsopp 2002). This lengthy time away from exercise can be detrimental to one's physical health. Additionally, there is an alarmingly high rate of re-injury of 36% (Hauret, Shippey et al. 2001).

There are many risk factors for sustaining a stress fracture including structure, nutrition, physiology and training. However, most researchers and clinicians agree that biomechanics play an important role in the development of this injury. Researchers have recently focused on loading variables during early stance. A recent meta-analysis of these studies indicates that these loading variables, such as load rates of the vertical ground reaction force as well as tibial shock, most often differentiate between injured and healthy cohorts (Zadpoor and Nikooyan 2011).

In addition to vertical loads, the tibia is simultaneously exposed to bending, shear and torsional loads with each footstrike (Ekenman, Halvorsen et al. 1998). Excessive torsional loading, specifically the free moment, has also been implicated in tibial stress fracture (TSF) incidence (Milner, Davis et al. 2006; Pohl, Mullineaux et al. 2008). Free moment is defined as the rotational force about a vertical axis caused by frictional forces between the shoe and the ground (Holden and Cavanagh 1991).

We have demonstrated that runners can reduce their vertical loads through sessions of real-time feedback (Crowell and Davis 2011). We have also shown that runners with excessive vertical loads can be trained to consistently reduce their tibial shock (TS) and vertical average loading rate (VALR) through a gait retraining protocol. This modification suggests that runners were successfully able to internalize cues needed for their new running gait pattern. In addition, these changes have persisted for up to 6 months (Davis et al., 2009). The protocol consisted of eight sessions of gait retraining using real-time visual feedback of their TS and verbal instruction to 'run softer'.

Although this retraining program has been effective at decreasing vertical loading, it may also be important to reduce torsional loading as well. A preliminary study indicated that runners with high vertical loading sometimes had associated high torsional loading as well (Fellin and Davis, 2009). Therefore, the purpose of this study was to determine if runners are able to decrease torsional loading following gait retraining to decrease vertical loading. We hypothesized that runners with high free moments will significantly reduce these moments following gait retraining. Furthermore, we hypothesized that these decreases in free moment will be correlated with the vertical load decreases.

Methods

Subjects

We conducted an a priori power analysis (alpha=0.05, beta=0.20), utilizing the difference between the TSF and control group from Milner and colleagues (Milner, Davis et al. 2006). To adequately power this study, 16 subjects were necessary. To be conservative, twenty runners were recruited through online advertisements, fliers posted on the University of Delaware campus, in person recruiting at local fitness centers and University of Delaware courses. For study inclusion, subjects were between 16-45 years of age, running ≥10 miles/week, and currently injury-free. Additionally, subjects rated their treadmill comfort on a visual analog scale at least 8/10, where 0 is very uncomfortable and 10 is totally comfortable with treadmill running. Prior to any data collections, we obtained written informed consent from each subject (Appendix A). Subjects who met the inclusion criteria were invited for a screening visit. Subjects who exhibited excessive vertical loading (tibial shock (TS) > 8 g's (Milner, Ferber et al. 2006) were invited to participate in this study. If both limbs exhibited TS > 8 g's, then the limb with the higher loading was used for the retraining portion of this study.

Baseline Data Collection

For the baseline collection, a tri-axial accelerometer was attached to the anteromedial aspect of the distal tibia of the retraining limb. Subjects ran along a 25m runway and traversed a forceplate (Bertec Corp., Columbus, OH, USA) at the center. Speed was monitored via photocells, and five trials of the retraining limb were collected at 3.70m/s ±5%. A VICON (Oxford, UK) motion analysis system captured kinetic data at 1200Hz.

Gait Retraining

Subjects then attended eight gait retraining sessions. Subjects ran at a self-selected pace on an instrumented treadmill (AMTI, Watertown, MA, USA) with an accelerometer tightly affixed on the distal tibia of their retraining limb. The accelerometer signal was displayed on a monitor. Subjects were instructed to keep their TS below a line, placed at 50% of their baseline TS.

We utilized a faded feedback paradigm designed to facilitate internalization of the new gait pattern (Winstein 1991). Run time gradually increased from 15 to 30 minutes over the eight sessions. Subjects had a minimum of one day off after two consecutive days of running, to prevent excessive muscle fatigue. Subjects received 100% visual feedback during the first four sessions. The feedback was gradually removed, such that subjects received only three minutes of feedback in the final session. Subjects refrained from running outside the laboratory during the gait retraining sessions.

Post retraining data collection

Following the completion of the eight gait retraining sessions, we conducted a post gait retraining collection and analyses as was described for the baseline collection.

Data Analysis

Utilizing a customized LabVIEW program we filtered the forceplate and accelerometer data at 50 Hz and 75 Hz, respectively. Then we calculated the peak adduction free moment (resisting toe-out) and TS for each of the five trials. For each subject, these five trial values were averaged together to obtain a mean value for each variable. This measure is repeatable with an ICC value of 0.942 from pilot data on ten subjects in our laboratory.

The variables of interest for vertical loading were vertical average loading rate (VALR), vertical instantaneous loading rate (VILR) and peak positive tibial acceleration (TS). The slope of the vertical ground reaction force was calculated from 20% to 80% of the impact peak value, in BW. This section is the most linear portion of the vertical ground reaction force curve. VALR was the average slope between those two points. VILR was calculated as the highest derivative between consecutive data points of the vertical ground reaction force from 20% to 80 % of the impact peak value. TS was calculated as the maximum positive value on the tibial acceleration curve from the accelerometer signal.

Statistical Analysis

The vertical loading variables of interest (AVLR, IVLR, and TS) and free moment adduction peak (FMADD) were compared pre- and post- gait retraining with dependent t-tests. The alpha level for significance was 0.05, with a trend defined as $0.05<p<0.010$. The change in free moment was correlated, using a Pearson’s correlation coefficient, with the change in vertical loading for AVLR, IVLR and TS. These changes were compared both for the entire group of subjects and those who had high FMADD pre-gait retraining.

Results

Our data indicated that as expected, vertical loads decreased with gait retraining (Table 1), with an average decrease of 32 %. However, torsional loads (FMADD) were unchanged following gait retraining in the entire subject group (Table 1). We had hypothesized only those runners with excessive torsional loads would decrease their loads. An examination of those runners with high torsional loads (n=10) revealed that FMADD was indeed significantly decreased following gait retraining (Table 2).

Table 1: Retraining variables of interest pre and post gait retraining for all twenty subjects (mean(SD)).

Variable	Pre	Post	Diff	p value
AVLR (BW/s)	96.3 (23.8)	70.1 (27.2)	26.1 (25.5)	0.000
IVLR (BW/s)	116.8 (28.8)	83.0 (32.1)	33.8 (31.2)	0.000
TS (g)	10.6 (2.5)	6.2 (2.6)	4.4 (2.7)	0.000
FMADD (BW*ht*10^{-3})	6.7 (3.4)	6.3 (2.9)	0.7 (1.6)	0.068

Table 2: Retraining variables of interest pre and post gait retraining for the ten subjects with high FMADD pre gait retraining (mean(SD)).

Variable	Pre	Post	Diff	p value
AVLR (BW/s)	90.0 (20.8)	66.9 (27.1)	23.0 (25.0)	0.017
IVLR (BW/s)	110.2 (24.9)	81.8 (32.0)	28.4 (26.6)	0.008
TS (g)	11.0 (2.0)	6.5 (1.9)	4.5 (3.0)	0.001
FMADD (BW*ht*10^{-3})	9.6 (2.1)	8.2 (1.9)	1.3 (1.5)	0.020

Correlations between changes in vertical loading and changes in torsional loads were small (range: -.144 to .164) and not significant in the group of twenty runners (Figures 1-3). However, the same correlations on the subset of ten subjects whose torsional loads were high pre gait retraining were modest (range: .665-.710) and statistically significant (Figures 4-6). These correlations indicate that subjects decrease their torsional loads less than they decrease their vertical loads.

Table 3: Pearson correlations of percent changes for retraining variables of interest: vertical average load rate (VALR), vertical instantaneous load rate (VILR), tibial shock (TS), free moment adduction peak (FMADD). Data are for all twenty subjects.

Variable		VALR	VILR	TS	FMADD
VALR	r value	1	.970	.835	-.010
	Sig.		.000	.000	.968
VILR	r value	.970	1	.852	-.144
	Sig.	.000		.000	.545
TS	r value	.835	.852	1	.164
	Sig.	.000	.000		.490
FMADD	r value	-.010	-.144	.164	1
	Sig.	.968	.545	.490	

Table 4: Pearson correlations of percent changes for retraining variables of interest: vertical average load rate (VALR), vertical instantaneous load rate (VILR), tibial shock (TS), free moment adduction peak (FMADD). Data are for the ten subjects with high FMADD pre gait retraining.

Variable		VALR	VILR	TS	FMADD
VALR	r value	1	.970	.845	.710
	Sig.		.000	.002	.022
VILR	r value	.970	1	.901	.698
	Sig.	.000		.000	.025
TS	r value	.845	.901	1	.665
	Sig.	.002	.000		.036
FMADD	r value	.710	.698	.665	1
	Sig.	.022	.025	.036	

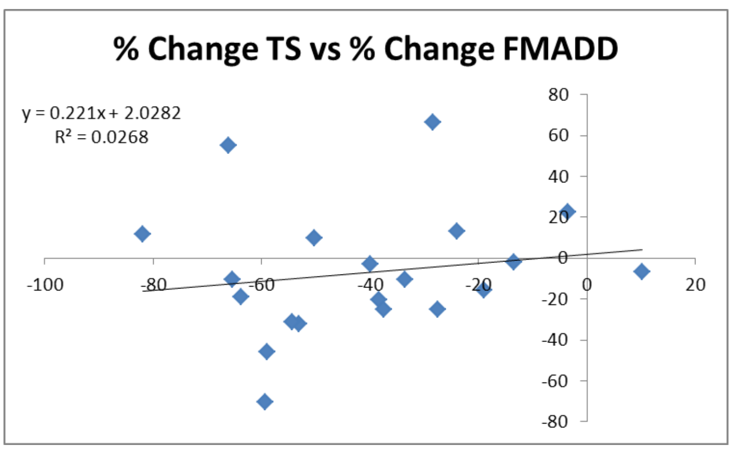

Figure 1: Percent change (pre to post gait retraining) in tibial shock (TS) versus percent change (pre to post gait retraining) in free moment adduction peak (FMADD) for all subjects. Note the absence of a relationship between the variables.

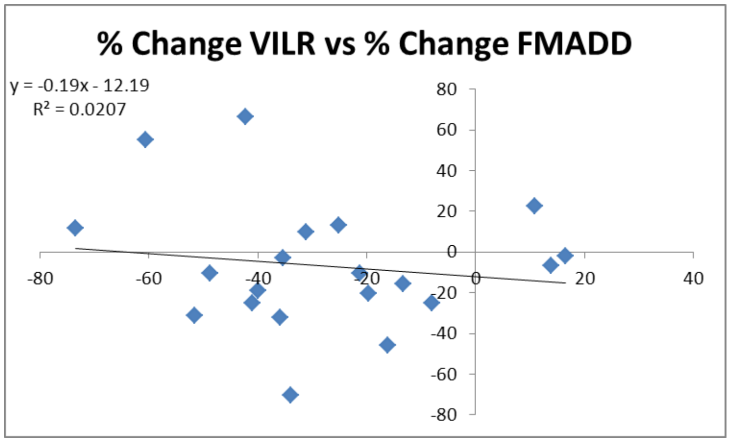

Figure 2: Percent change (pre to post gait retraining) in vertical instantaneous load rate (VILR) versus percent change (pre to post gait retraining) in free moment adduction peak (FMADD) for all subjects. Note the absence of a relationship between the variables.

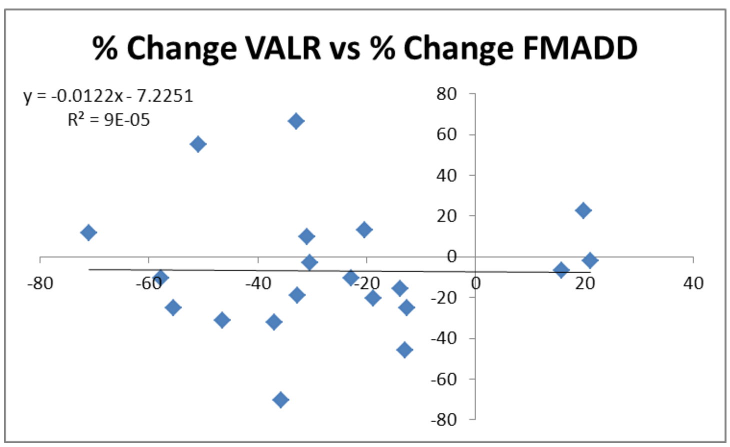

Figure 3: Percent change (pre to post gait retraining) in vertical average load rate (VALR) versus percent change (pre to post gait retraining) in free moment adduction peak (FMADD) for all subjects. Note the absence of a relationship between the variables.

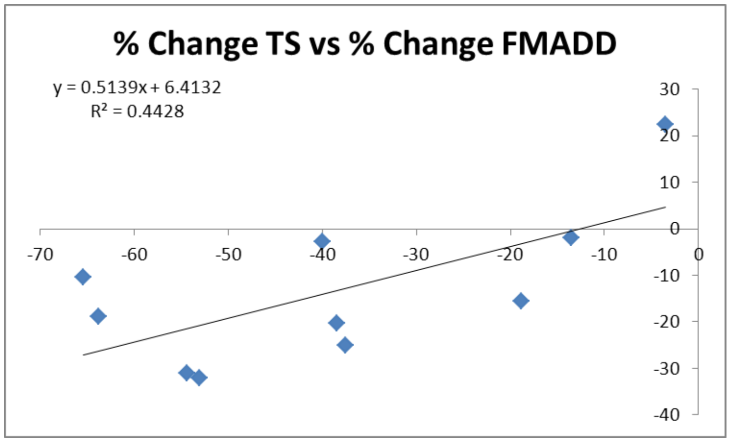

Figure 4: Percent change (pre to post gait retraining) in tibial shock (TS) versus percent change (pre to post gait retraining) in free moment adduction peak (FMADD) for subjects with high FMADD pre gait retraining. Note the modest and statistically significant relationship between the variables.

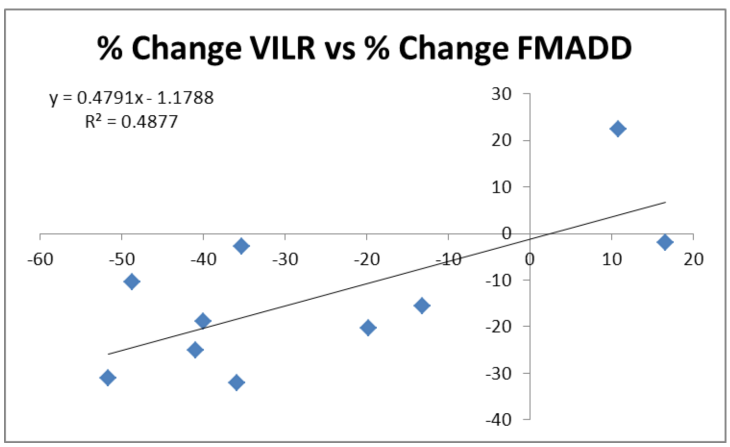

Figure 5: Percent change (pre to post gait retraining) in vertical instantaneous load rate (VILR) versus percent change (pre to post gait retraining) in free moment adduction peak (FMADD) for subjects with high FMADD pre gait retraining. Note the modest and statistically significant relationship between the variables.

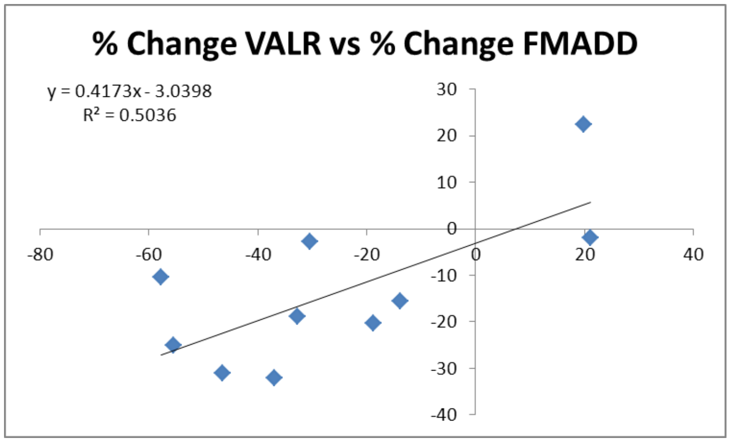

Figure 6: Percent change (pre to post gait retraining) in vertical instantaneous load rate (VILR) versus percent change (pre to post gait retraining) in free moment adduction peak (FMADD) for subjects with high FMADD pre gait retraining. Note the modest and statistically significant relationship between the variables.

Discussion

This study examined the effect of gait retraining to decrease vertical loads on torsional loads pre and post gait retraining. Our results supported our hypothesis that those runners with high FMADD pre gait retraining would reduce those high free moments following gait retraining. Furthermore, our results supported our secondary hypothesis that subjects' decreases in torsional loads would be correlated to decreases in vertical loads. It is likely that these runners with excessive loads in both planes of motion are at higher risk of injury as each of these loads are risk factors for TSF. Torsional load changes with gait retraining had not been previously studied.

Vertical load decreases were similar to the literature. The subjects decreased their tibial shock 40% on average, which was slightly less than their target during the feedback sessions of a 50% reduction. Additionally, the decrease in vertical load rate from this study, around 30%, is similar to what has been reported previously (Crowell and Davis 2011). Therefore, these subjects appear to demonstrate typical vertical load decreases following gait retraining. Although vertical load decreased as expected, torsional load changes had not been previously examined in the literature.

It is important to note that the loads did not increase with the retraining as altering one aspect of gait could negatively influence other aspects. Only a trend towards a decrease in torsional loads following gait retraining was noted across all subjects. However, the subgroup of runners who exhibited high torsional loads at baseline did indeed markedly and significantly reduce their torsional loads following retraining. The reductions were less than those seen in the vertical loading. However, 5/10 subjects post-retraining torsional values fell within normal limits, thereby reducing their risk for torsional loading injuries (Milner, Davis et al. 2006). With their high torsional loads at baseline, these runners had a greater potential for reduction than those whose values were not abnormal.

This gait retraining protocol consisted of eight sessions. It is possible that the effects on vertical and torsional loading would be different if the gait retraining protocol was a different length or consisted of additional feedback. As the sample size was low, additional subjects are necessary to further validate these findings.

We have shown that reductions in vertical loading persist out to six months (Davis et al., 2009) While torsional loading was reduced post-retraining, we did not assess the persistence of these changes. Future studies should include a follow-up assessment to determine if torsional loading also remains reduced over the long-term.

Conclusion

In this cohort, subjects with excessive torsional loads pre-gait retraining significantly decreased these loads following gait retraining aimed at decreasing vertical loads. The decrease in torsional loads was also significantly related to the decrease in vertical loads following gait retraining. Torsional loads were decreased to a smaller magnitude than vertical loads, but in 5/10 runners they still fell within normal limits following the retraining.

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Chapter 3

EFFECT OF GAIT RETRAINING ON VERTICAL LOADING OF THE UNTRAINED, CONTRALATERAL LIMB DURING RUNNING

Abstract

Tibial stress fractures are serious running injury that requires 6-8 weeks off from training. Excessive vertical loading such as high vertical load rates and tibial shock have been linked to tibial stress fracture risk. Many runners exhibit excessive vertical load rates bilaterally, placing them at an even higher risk of injury. Gait retraining to decrease vertical loading has been successful in decreasing loads on the trained limb, but the effect on the contralateral limb is unknown. Therefore, the purpose of this study was to examine changes in contralateral limb vertical loading following a gait retraining protocol to decrease vertical loads on the trained limb. **Methods**: Ten runners with high vertical loading were recruited for this study. They underwent eight sessions of real-time visual feedback designed to decrease vertical loads on the trained limb. Pre and post gait retraining load rates and tibial shock were measured on the trained and untrained limbs during treadmill running at a test speed of 3.35 m/s, as well as the subject's self-selected running speed. **Results**: The ANOVA results indicated no interaction or limb effect for all variables. There was a main effect of time on their trained and untrained limbs for all variables. At the test speed, subjects significantly

decreased vertical load rates by 21-22% on both limbs. At the self-selected speed, load rates decreased 34-37% on both limbs. Tibial shock decreases were similar to the load rate decreases. **Conclusion**: Tibial shock and vertical load rates decrease on the untrained, contralateral limb following a gait retraining protocol to decrease vertical loads on the trained limb. These untrained limb changes occur during treadmill running, and overall they are of similar magnitude to the trained limb load changes.

Introduction

Approximately 16.4 million Americans are engaged in the sport of running today (SGMA). Unfortunately, it has been reported that up to 79% of runners sustain an injury in a given year (van Gent, Siem et al. 2007). Stress fractures are one of the most common injuries, with a 4-22% annual incidence reported in runners (Bennell, Malcolm et al. 1996; Arendt, Agel et al. 2003). Stress fractures occur most frequently in the tibia (Taunton, Ryan et al. 2002). Additionally, there is an alarmingly high rate of re-injury of 36% (Hauret, Shippey et al. 2001). A recent meta-analysis indicates that biomechanical loading variables, such as load rates of the vertical ground reaction force as well as tibial shock, most often differentiate between injured and healthy cohorts (Zadpoor and Nikooyan 2011).

Runners often exhibit high loading bilaterally (Zifchock, Davis et al. 2006). However, it is difficult for the subject to concentrate on retraining both limbs at the same time. Therefore, our recent gait retraining studies have addressed training the limb with the highest impact loading, without attention to the untrained limb (Crowell and Davis 2011). As the regulation of human locomotion requires interlimb coordination (Dietz 1992; Dietz 2002; Dietz, Muller et al. 2002), there may be cross transfer effects to the untrained limb. Multiple unilateral training protocols have reported cross transfer effects to the untrained limb (Dietz 1992; Ting, Kautz et al. 2000; Lee, Gandevia et al. 2009; Savin, Tseng et al. 2010). A study, which applied a perturbation to one leg, resulted in bilateral step length changes during the perturbation as well as after effects (Savin, Tseng et al. 2010). The step length on the perturbed side decreased while the step length on the unperturbed side increased, which resulted in no change in stride length. Unilateral step decreases are quite common with some pathologies, such as stroke and osteoarthritis. Therefore, it is impressive this perturbation resulted in bilateral changes in step length. A recent study (Lee, Gandevia et al. 2009) reported that strength training of one limb resulted in increased strength of the untrained limb. However, the strength gains in the untrained limb were less than that found for the trained limb. Dietz and colleagues found that unilateral stepping movements produced bilateral lower limb muscle activity (Dietz, Muller et al. 2002). Furthermore, Ting and colleagues studied healthy subjects performing unilateral cycling and found these subjects exhibited similar muscle activity between the pedaling and non-pedaling limbs (Ting, Kautz et al. 2000). Therefore, it is possible that the changes in mechanics observed in the retrained limb may also be exhibited in the untrained, contralateral limb.

The purpose of this study was to identify changes in the contralateral, untrained limb following a gait retraining protocol designed to decrease vertical loading on the trained limb. We hypothesized that tibial shock, vertical average load rate and vertical instantaneous load rate would decrease on the untrained, contralateral limb, but to a lesser degree than on the trained limb.

Methods

Subjects

Ten runners were recruited through online advertisements, fliers posted on the University of Delaware campus, in person recruiting at local fitness centers and University of Delaware courses. We conducted an a priori power analysis (alpha=0.05, beta=0.20), utilizing an effect size of 1.2 from our preliminary data on five subjects. To adequately power this study, 6 subjects were necessary. For study inclusion, subjects were between 16-45 years of age, running ≥10 miles/week, and currently injury-free. Additionally, subjects rated their treadmill comfort on a visual analog scale at least 8/10, where 0 is very uncomfortable and 10 is totally comfortable with treadmill running. Prior to any data collections, we obtained written informed consent from each subject (Appendix A). Subjects who met the inclusion criteria were invited for a screening visit. Subjects who exhibited excessive vertical loading (tibial shock (TS) > 8 g's (Milner, Ferber et al. 2006) were invited to participate in this study. If both limbs exhibited TS > 8 g's, then the limb with the higher loading was used for the retraining portion of this study.

Baseline Data Collection

For the baseline collection, a tri-axial accelerometer was attached to the anteromedial aspect of the distal tibia of both limbs. Next, the subject ran on an instrumented treadmill (AMTI, Watertown, MA, USA) at a self-selected running speed for 3 minutes, following which 15 consecutive strides of data were collected. Subjects then continued running at 3.35 m/s (8 min/mile pace) for three minutes, following which 15 consecutive strides of data were collected. Kinetic data from the forceplate and accelerometers were sampled at 1200 Hz using a motion analysis system (VICON, Centennial, CO, USA).

Gait Retraining

Subjects attended eight gait retraining sessions. Subjects ran at a self-selected pace on an instrumented treadmill (AMTI, Watertown, MA, USA) with an accelerometer tightly affixed on the distal tibia of their retraining limb. The accelerometer signal was displayed on a monitor. Subjects were instructed to keep their TS below a line, placed at 50% of their baseline TS.

We utilized a faded feedback paradigm designed to facilitate internalization of the new gait pattern (Winstein 1991). Run time gradually increased from 15 to 30 minutes over the eight sessions. Subjects had a minimum of one day off after two consecutive days of running, to prevent excessive muscle fatigue. However, subjects were permitted to space out the protocol according to their schedule as long as they finished the running sessions within three weeks of time. Subjects received 100% visual feedback during the first four sessions. The feedback was gradually removed, such that subjects received only three minutes of feedback in the final session. In each session with partial feedback, the feedback time was divided into three equal bouts, one at the start, one in the middle of the session and one at the end of the session. Subjects refrained from running outside the laboratory during the gait retraining sessions.

Post retraining data collection

Following the completion of the eight gait retraining sessions, we conducted a post gait retraining collection and analyses as described for the baseline collection.

Data Analysis

We processed both trained limb and untrained, contralateral limb data. We analyzed the first five non-consecutive strides of data from the treadmill data collected. Utilizing customized LabVIEW code we filtered our forceplate data at 50 Hz. The variables of interest were vertical average loading rate (VALR), vertical instantaneous loading rate (VILR) and peak positive tibial acceleration (TS). The slope of the vertical ground reaction force was then calculated from 20% of the impact peak value to 80% of the impact peak value, in BW. This section is the most linear portion of the vertical ground reaction force curve. VILR was calculated as the highest derivative between consecutive data points of the vertical ground reaction force from 20% to 80 % of the impact peak value. TS was calculated as the maximum positive value on the tibial acceleration curve from the accelerometer signal.

Statistical Analysis

We used a 2 factor (limb x time), within subjects ANOVA to compare the three loading variables of interest (VALR, VILR, TS) at both the test speed and self-selected speed. The two levels of limb were trained limb and untrained, contralateral limb. The two levels of time were pre and post gait retraining. We performed planned comparisons of paired t-tests to identify differences in the loading variables pre and post gait retraining within each limb. We also calculated percent differences for pre to post gait retraining.

Results

There was no interaction between limb and time for any of the variables at either of the speeds. Therefore, we examined main effects for each variable of interest. Our results supported our hypotheses that tibial shock and load rates would decrease on the contralateral, untrained limb. The repeated measures ANOVA revealed a main effect of time for each of our variables of interest, TS, VALR, and VILR (Table 5). Post hoc tests indicated that for each variable, on both limbs, there was an effect of time (Figures 7-9). The percent changes indicated that subjects decreased their vertical loads moderately during treadmill running following gait retraining. Subjects load rates decreased 22-24% on both limbs. However, TS decreased 26% on their TL compared to only 10% on their CL. There was no main effect of limb (Table 6).

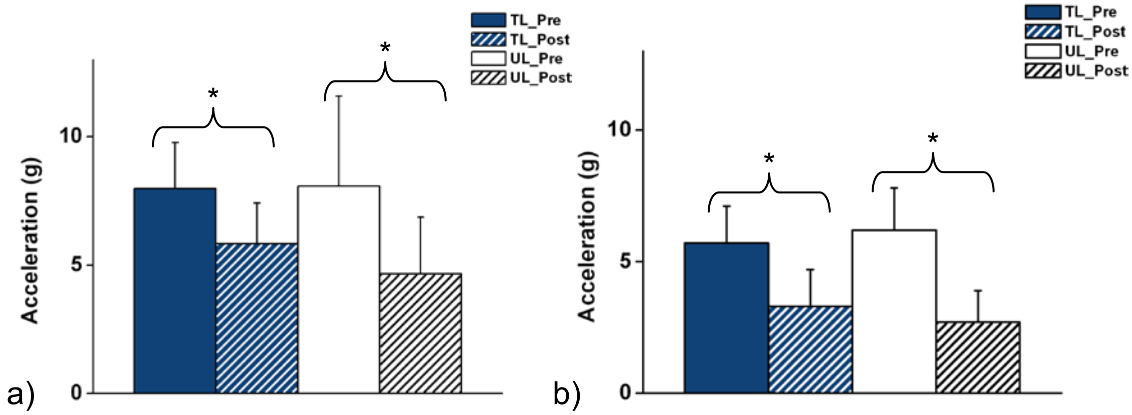

Figure 7: Tibial shock (TS) pre and post gait retraining for the trained (TL) and untrained (UL) limbs for a) test speed (3.35 m/s) and b) self-selected speed. Note the significant decrease in TS on both limbs and at both speeds. Asterisks indicate values are significantly different (p <0.05).

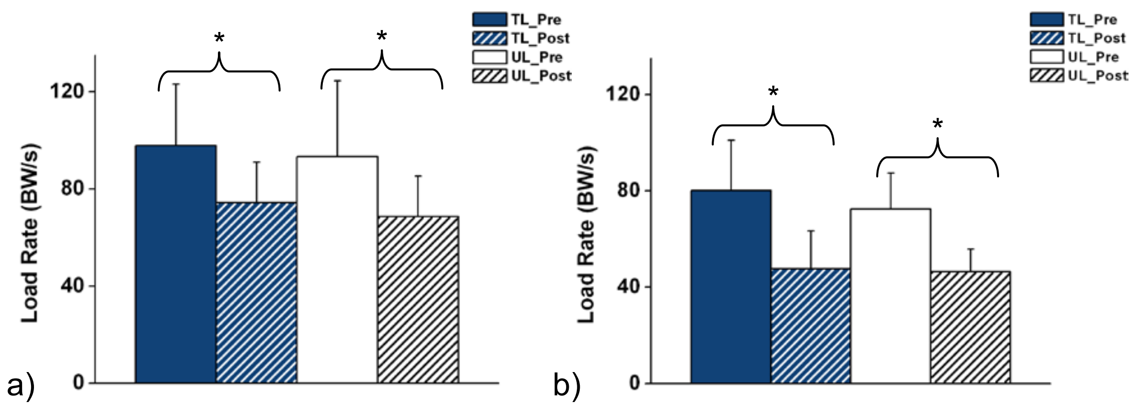

Figure 8: Vertical instantaneous load rates (VILR) pre and post gait retraining for the trained (TL) and untrained (UL) limbs for (a) test speed and (b) self-selected speed. Note the significant decrease in VILR on both limbs and at both speeds. Asterisks indicate values are significantly different (p <0.05).

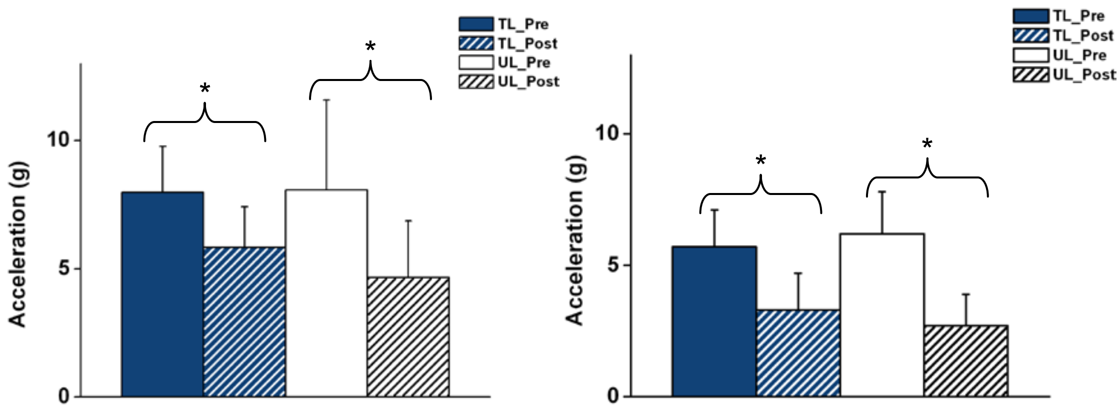

Figure 9: Vertical average load rates (VALR) pre and post gait retraining for the trained (TL) and untrained (UL) limbs for (a) test speed and (b) self-selected speed. Note the significant decrease in VALR on both limbs and at both speeds. Asterisks indicate values are significantly different ($p < 0.05$).

Table 5: ANOVA results from limb (trained and contralateral) and time (pre and post gait retraining) for test speed (3.35 m/s) and self-selected speed. TEST=test speed, SELF=self-selected speed, TS=tibial shock, VALR=vertical average load rate, VILR=vertical instantaneous load rate.

Factor	Variable	p value TEST	p value SELF
Time	TS	.014	.008
	VALR	.014	.004
	VILR	.008	.003
Limb	TS	.273	.922
	VALR	.213	.171
	VILR	.239	.229
Limb x Time	TS	.666	.136
	VALR	.870	.228
	VILR	.828	.103

Table 6: Percent change following gait retraining for variables of interest, mean (SD) at test speed (3.35 m/s) and self-selected speed. TEST= test speed, SELF= self-selected speed, TS=tibial shock, VALR=vertical average load rate, VILR=vertical instantaneous load rate.

Variable	Limb	% Change TEST	% Change SELF
TS	TL	-26 (18)	-36 (30)
	CL	-32 (36)	-52 (26)
VALR	TL	-22 (20)	-37 (22)
	CL	-22 (21)	-36 (17)
VILR	TL	-21 (18)	-38 (21)
	CL	-22 (17)	-34 (16)

Discussion

This study investigated the effect of a unilateral gait retraining protocol on the untrained contralateral limb. Our results supported our hypotheses that runners would reduce vertical loads following gait retraining on their untrained, contralateral limb. However, our hypotheses that these load reductions would be lesser on the untrained, contralateral limb than the trained limb were only partially supported. All of our loading variables decreased although the loading decreases did not differ between limbs. Changes on the contralateral limb as a result of gait had not been previously studied.

Vertical load decreases, in both the trained and contralateral limbs, were less than what has been reported in overground running (Crowell and Davis 2011). On their trained limb, the subjects decreased their tibial shock 26% on average at the test speed, which was only half of their target reduction, of 50%, during the feedback sessions. In contrast, Crowell and Davis reported a 48% reduction in tibial shock following gait retraining (Crowell and Davis 2011). Additionally, the decrease in vertical load rates from this study at the test speed, around 25%, are slightly less than the 32-34% reported previously (Crowell and Davis 2011). However, the subjects in this cohort were tested during treadmill running instead of overground running. Furthermore, the subjects in this study ran at a slightly slower test speed (3.35 m/s versus 3.7 m/s), which may account for the smaller decreases on the trained limb observed in this study.

Another explanation for the reduced load changes following gait retraining compared to the literature may be related to the speed of running. We allowed all of the subjects to run at a self-selected speed during the training sessions. With the increased concentration required during the retraining, this speed was typically slower than our standard testing speed. Subjects demonstrated larger percent degreases in loading at the self-selected speed than the test speed.

For all of our loading variables, the effect of the gait retraining was similar bilaterally. These findings are consistent with other reports. In a walking perturbation study, the mean change for the group varied from the same magnitude to only half the magnitude on the unperturbed limb depending on the variable (Savin, Tseng et al. 2010). Other studies constrained the untrained limb (Ting, Kautz et al. 2000; Dietz, Muller et al. 2002) whereas in this study the untrained limb was not constrained. Therefore, it is possible that the untrained limb in this study was able to perform similarly to the trained limb as it did not have any constraints.

At the self-selected speed, the subjects' percent decreases were larger than at the test speed. As the gait retraining took place at a self-selected speed, it is possible that subjects were better able to make gait changes at this speed. Gait kinematics and kinetics vary with speed, which may explain why subjects had larger decreases at their self-selected speed.

As the subjects were able to alter their gait at the test speed, it appears the subjects were able to generalize their learning of gait retraining.

This study was conducted during treadmill running and it is unknown whether loading will also be reduced in the contralateral limb during overground running. Previous gait retraining studies have indicated that the reduced loading in the trained limb during treadmill running was carried over to overground running (Crowell and Davis 2011). Therefore, it is possible that changes in the contralateral limb will carry over to overground running.

At this time, we do not know whether the changes in the contralateral, untrained limb persist beyond the gait retraining. However, previous studies have documented load reductions in the trained limb for up to 6 months following retraining (Davis et al. 2009). Future studies should incorporate a follow-up period to determine whether the reductions in loading seen in the contralateral limb persist beyond the intervention.

This gait retraining protocol consisted of eight running sessions of visual feedback. The effects on the loading of the trained and untrained limb loads may be different if the gait retraining protocol utilized different feedback methods or additional sessions. These results need to be further validated in a larger group of subjects.

Conclusion

Tibial shock and vertical load rates decrease on the untrained, contralateral limb following a gait retraining protocol to decrease vertical loads on the trained limb during treadmill running. These untrained limb changes are similar in magnitude to the trained limb changes for load rates and tibial shock at both a standardized test speed and self-selected speed.

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Chapter 4

EFFECT OF GAIT RETRAINING ON TIBIAL STRAIN RATES DURING RUNNING

Abstract

Tibial stress fractures are a serious and common injury that runners sustain. Excessive external loading, characterized by high tibial shock and vertical load rates, has been linked to an increased risk of tibial stress fractures. However, external loading does not directly indicate bony loads, which cause stress fractures directly through excessive loads over time. Gait retraining to decrease external, vertical loading has been successful and in a simple beam model indicated that tibal strain rates decreased at specific locations on the tibia. However, the strain rate distribution in the region where stress fractures occur most often, the midshaft to distal third, remains uncharacterized. Therefore, the purpose of this study was to compare tibial strain rates from the midshaft to the distal third of the tibia pre and post gait retraining. We hypothesized that tibial strain rates would decrease following gait retraining. **Methods**: Five subjects with excessive vertical loading were recruited for this study. They completed eight sessions of gait retraining, which consisted of real-time visual feedback of their tibial shock. Vertical load rates and tibial shock were compared between baseline and post-retraining. A finite element model was used to calculate strain rates along the midshaft to distal

third of the tibia. **Results**: All subjects decreased their external loading by 19-57%. Tibial strain rate decreases were mixed. Four subjects decreased their tibial strain rates in the region of interest by 10-48%, and one subjects increased tibial strain rates by 13% across the region of interest. **Conclusion**: Tibial strain rates may decrease following gait retraining to decrease vertical loads. 4/5 of these subjects demonstrated that pattern. Additional subjects are needed to further validate these findings.

Introduction

Running is a popular form of exercise, which about 16.4 million Americans participate in (SGMA). Unfortunately, up to 79% of runners sustain an injury each year(van Gent, Siem et al. 2007). One of the most common injuries is a stress fracture, which has a 4-22% annual incidence reported in runners (Bennell, Malcolm et al. 1996; Arendt, Agel et al. 2003). Stress fractures most commonly occur in the tibia (Taunton, Ryan et al. 2002). Unfortunately, up to 36% of runners sustaining a stress fracture sustain an additional stress fracture (Hauret, Shippey et al. 2001). A recent meta-analysis found that risk factors for tibial stress fracture injuries include loading variables in the early stance phase of running (Zadpoor and Nikooyan 2011). These variables include loading rates of the vertical ground reaction force as well as tibial shock.

Measurement of the effect of gait retraining on external loads does not provide a direct indication of the loads that the tibia experiences. It is possible to directly measure loads, such as tibial strains with a strain gauge.

However, these devices have to be attached directly to the bone. Therefore, the process is invasive, can be painful, and the strain gauges may influence the subject's motion. A non-invasive alternative is to use a model of the tibia to estimate these bony loads.

The earliest models of the tibia were two-dimensional. In 1990, Scott and Winter designed a tibial model to analyze the loading of the distal third of the lower leg during running (Scott and Winter 1990). The authors concluded that the plantarflexors protect the tibia by counteracting bending and shear forces caused by the ground reaction force during running. In another study, Sasimontonkul and colleagues used a two-dimensional model of the lower limb to calculate bone contact forces during running (Sasimontonkul, Bay et al. 2007). They found that the muscle forces magnified the compressive forces produced by the ground reaction force. Additionally, the muscle forces provided a protective effect by inducing shear in the opposite direction of the ground reaction force produced shear. Although results of these two dimensional methods were useful, they provided an incomplete description of the loading of the tibia during running.

There have been several three-dimensional studies of tibial loading in running. The earliest study combined subject specific geometry, obtained from magnetic resonance imaging (MRI) with ground reaction force data (van den Bogert and Nigg, 1993). These authors observed a peak in tibial stress around the vertical impact peak in early stance. They also found that the anterior tibia was in tension and the posterior was in compression for the majority of stance. DeWoody and associates used a forward dynamics approach and found that tibial stresses were underestimated by one order of magnitude if muscle forces were omitted (DeWoody, Martin et al. 2001). Furthermore, they found that the peak stresses occurred in early stance, before the timing of the peak ground reaction force. Crowell examined peak tibial strain rates in running, using an inverse dynamics method combined with a simple beam model (2009). He found a decrease in the peak strain rates, which occurred in early stance. Consistent with van den Bogert and Nigg (1993) he also found that the tibia was in tension on the anterior side and compression on the posterior side. Two additional studies by Edwards and colleagues examined tibial loading at the peak ground reaction force (Edwards, Taylor et al. 2009; Edwards, Taylor et al. 2010). These authors also found that the tibia was in tension on the anterior side and compression on the posterior side, which is consistent with strain gauge data (Burr, Milgrom et al. 1996). However none of these models examined the entire region of the tibia, from the midshaft to its distal third, during the initial loading phase of running. Therefore, the purpose of this study was to examine changes in strain rates on the tibial following gait retraining from the midshaft to distal third region. We hypothesized that the strain rates would decrease following gait retraining aimed at reducing external loads.

Methods

Subjects

Five runners were recruited from the local university community. All subjects were between 16-45 years of age, running ≥10 miles/week, and currently injury-free. Additionally, subjects rated their treadmill comfort on a visual analog scale at least 8/10, where 0 is very uncomfortable and 10 is totally comfortable with treadmill running. Prior to any data collections, we obtained written informed consent from each subject (Appendix A). Subjects who met the inclusion criteria were invited for a screening visit. Subjects who exhibited excessive vertical loading (tibial shock (TS) > 8 g's (Milner, Ferber et al. 2006) were invited to participate in this study. If both limbs exhibited TS > 8 g's, then the limb with the higher loading was used for the retraining portion of this study.

Baseline Data Collection

For the baseline collection, a tri-axial accelerometer was attached to the anteromedial aspect of the distal tibia of the retraining limbElectromyographic (EMG) data (Motion Labs, Baton Rouge, LA) were collected from the subject's tibialis anterior, soleus, medial and lateral gastrocnemius on the same limb. A total of 24 reflective markers were placed on the subject's pelvis, and bilaterally to the thigh, shank and rearfoot. We utilized a marker placement device to place the markers at each session in order to improve the day-to-day reliability of marker placement (Noehren, Manal et al. 2010). Anatomical markers included iliac crests, greater trochanters, lateral and medial femoral condyles, lateral and medial tibial plateaus, lateral and medial malleolus, distal heel, first and fifth metatarsal heads, and toe marker bilaterally. Individual tracking markers were then applied to the torso and tracking markers on shells secured with wraps to thigh and shank segments bilaterally.

Subjects ran along a 25m runway and traversed a forceplate (Bertec Corp., Columbus, OH, USA) at the center. Speed was monitored via photocells, and five trials of the retraining limb were collected at 3.70m/s ±5%. A VICON (Oxford, UK) motion analysis system captured kinematic, kinetic, and EMG data at 240, 1200 and 1200Hz, respectively.

Gait Retraining

Subjects then attended eight gait retraining sessions. Subjects ran at a self-selected pace on an instrumented treadmill (AMTI, Watertown, MA, USA) with an accelerometer tightly affixed on the distal tibia of their retraining limb. The accelerometer signal was displayed on a monitor. Subjects were instructed to keep their TS below a line, placed at 50% of their baseline TS (Figure 10).

Figure 10: Example of real-time feedback from accelerometer presented to subjects while they ran on the treadmill.

We utilized a faded feedback paradigm designed to facilitate internalization of the new gait pattern (Winstein 1991). Run time gradually increased from 15 to 30 minutes over the eight sessions. Subjects had a minimum of one day off after two consecutive days of running in order to prevent excessive muscle fatigue. All subjects were required to finish the running sessions within three weeks of time. Subjects received 100% visual feedback the first four sessions. The feedback was gradually removed, such that subjects received only three minutes of feedback in the final session. Subjects refrained from running outside the laboratory during the gait retraining sessions.

Post retraining data collection

Following the completion of the eight gait retraining sessions, we conducted a post gait retraining collection and analyses as was described for the baseline collection.

Data Analysis

We analyzed the pre- and post-training data using musculoskeletal and finite element modeling. The most representative trial for pre-gait retraining and the most representative trial for post-gait retraining were chosen for analysis. The marker and forceplate data were filtered at 8 and 50 Hz, respectively in Visual 3D (C-motion, Germantown, MD, USA). In Visual 3D, inverse kinematics was performed on the gait data. Then the data were exported from Visual 3D into a format for OpenSim 1.9.1 (Delp, Anderson et al. 2007) with an adjustment for the trunk angle in the standing calibration trial.

In OpenSim, we scaled their default eight segment, 13 degrees of freedom (DOF) model using the subject mass. Each lower extremity contained five DOF, one at the ankle (dorsiflexion/plantarflexion), one at the knee (flexion/extension) and three at the hip. The lumbar motion had 3 DOF. The model contained 92 musculotendon actuators (Delp, Loan et al. 1990; Anderson and Pandy 1999).

After scaling the model, we applied a residual reduction algorithm (RRA) to the inverse kinematic data. RRA calculates the joint moments necessary to track the subject's motion. Specifically, it uses the inverse dynamics result and decreases the residuals through small modifications to the mass properties of the model and the joint kinematics. We performed multiple iterations of RRA altering the segment weights for each iteration to minimize the difference between the experimental data and model data. Then we used computed muscle control (CMC), a forward dynamics method, to estimate the muscle activations to produce the kinematic patterns obtained from RRA (Thelen and Anderson 2006). This process employed a cost function that minimizes the sum of the square of the muscle activations. It simultaneously accounted for muscle activation and contractile dynamics to resolve the muscle redundancy present in the model (Zajac 1989) by solving a static optimization problem (Crowninshield and Brand 1981). The muscle activations obtained were compared with our EMG data, as well as data from the literature (Cappellini, Ivanenko et al. 2006; Hamner, Seth et al. 2010) to confirm the results are reasonable in terms of timing and approximate magnitude. If necessary, the muscle excitations were constrained, and CMC was re-run to ensure the muscle activations predicted were appropriate. These data were input into the joint reaction analysis tool, which calculated joint contact forces for the ankle in the tibia coordinate system. As the fibula only accounts for 10% of the ankle joint contact force during running (Sasimontonkul, Bay et al. 2007), the calculated joint contact forces were multiplied by 0.9 to approximate the weight borne by the tibia.

The Virtual Animation of the Kinematics of the Human (VAKHUM) dataset of the tibia was used for the finite element analysis. The finite element meshes consist of 8 node hexahedral elements with 6 mesh refinements. Based upon pilot data and previous research (Edwards, Taylor et al. 2009; Edwards, Taylor et al. 2010) the 3rd mesh refinement from the VAKHUM project provided sufficient detail for this analysis. This mesh refinement included 8221 C3D8 elements and 9563 degrees of freedom, provided sufficient detail for a solution to converge. In the tallest subject, the element edge width in the vertical direction was approximately five mm.

Prior to conducting analyses on the tibia model, we scaled the generic tibia from the VAKHUM project to the tibia length for each subject calculated in Visual 3D. Using a generic model scaled to the subject's tibia size is adequately robust for a within-subject design such as this. We then defined each material as trabecular or cortical bone based upon a density cutoff of 1.2 g/cm3 (Beaupre, Orr et al. 1990). Next, we set the Young's Modulus for trabecular and cortical bone to 10.4 GPa and 18.6 GPa (Rho, Ashman et al. 1993), respectively, with a Poisson's ratio of 0.3 for all bone (Edwards, Taylor et al. 2010).

After the model was scaled to the subject, within Abaqus 6.7-1 (Simulia, Providence, RI), we constrained the proximal end of the tibia to prevent motion (Figure 11). We then applied the ankle joint contact force, obtained from OpenSim, as a concentrated load to the distal end of the tibia. This was repeated for each stance time point (at 240 Hz) up to 25% stance, using the dynamic implicit command with a half step tolerance equal to the maximum vertical force applied. We chose to limit the analysis to 25% of stance, as a recent meta-analysis found loading in early stance, was important in stress fracture incidence while the peak force was not (Zadpoor and Nikooyan 2011).

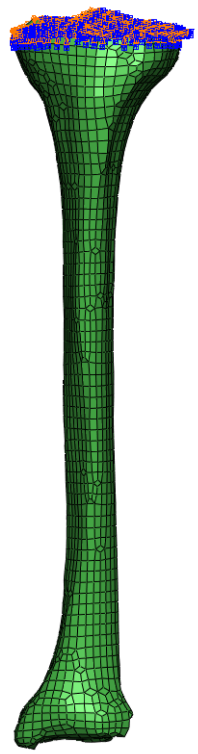


Figure 11: Boundary conditions for finite element model. The proximal end of the tibia was constrained to prevent displacement.

These analyses were repeated for the three trials from the post gait retraining data collection.

Statistical Analysis

Due to the small sample size, we analyzed the results descriptively. We calculated the maximum principle strain rates (for tension and compression) for the region of interest along the medial and posterior aspects of the tibia between the midshaft and distal third. Changes between baseline and post-retraining were determined. These changes were compared to the vertical loading decreases in external loading variables (TS, VALR, and VILR and VIP) during overground running.

Results

The external loads in early stance were reduced by 45% following gait retraining (Table 7). The impact peak was noticeably attenuated in these subjects (Figure 12). There was also an associated reduction in the joint contact force that coincided with the timing of the vertical impact peak (Figure 13 and 14). The muscle activations within the first 25% of stance only needed to be constrained for the TA in 4/5 subjects. The onset timing for the other muscles was appropriately predicted by OpenSim.

Table 7: Subject external load percent changes pre to post gait retraining and kinematic strategy utilized to cause these external load changes. Abbreviations: inc-increase; dec-decrease, DF-dorsiflexion; FS-footstrike; avg-average.

Subject	TS	VALR	VILR	Overall Change	Kinematic Strategy
1	-23	-14	-20	-19	Inc ankle DF & dec knee flexion at FS
2	-63	-32	-47	-56	Forefoot striker
3	-65	-35	-33	-44	Inc ankle DF, dec knee flexion at FS
4	-41	-58	-43	-47	Forefoot striker
5	-65	-53	-54	-57	Inc ankle DF, inc knee flexion at FS
Avg	-51	-38	-39	-45	N/A

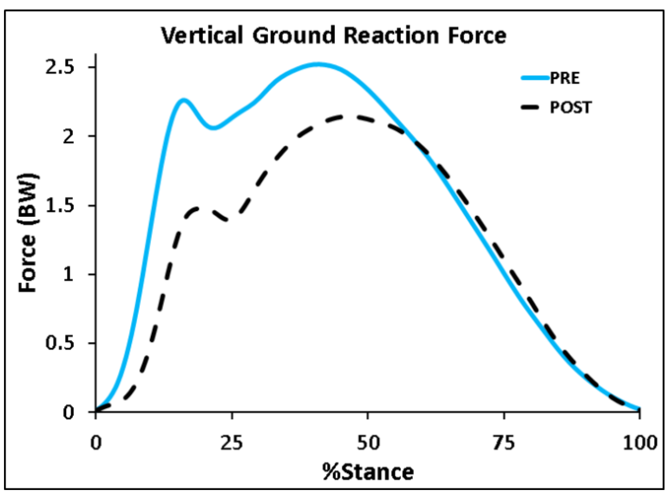


Figure 12: Vertical GRF pre and post gait retraining for subject 3. Note the impact peak is nearly as high in magnitude at the peak GRF pre-gait retraining.

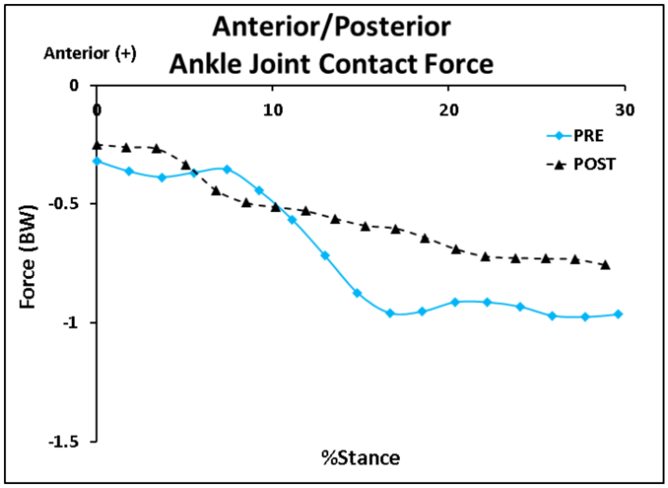


Figure 13: Ankle joint contact force pre and post retraining for the anterior/posterior direction for subject 3. These forces are in the tibial coordinate system and are acting on the tibia.

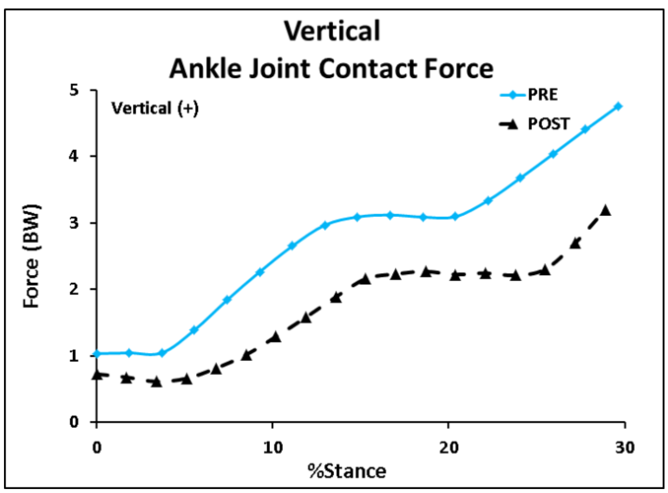


Figure 14: Ankle joint vertical contact force pre and post retraining for a subject 3. These forces are in the tibial coordinate system and are acting on the tibia. Note the apparent decrease in rate of loading in the vertical graph and decreased peak between 10-15% of stance.

In general, the highest strain rates were closest to the midshaft. Strain rates gradually decreased from there to the distal third. As expected, the anterior and lateral regions were in tension and the medial and posterior regions were in compression. The strain rate magnitudes were highest anteriorly and posteriorly with lower values medially and laterally (Figures 15-17).

While all subjects demonstrated a reduction in their external loading, the tibial strain rate data were more variable. Following gait retraining, four of the five subjects decreased their strain rates between the midshaft and distal third (Table 8). One of the five subjects had similar external load reductions and tibial strain rate reductions. One subject’s average strain rate decrease (-48%) was larger than the external load decrease (-35%). Two subjects exhibited external load reduction about three times as large as the decrease in strain rate. The final subject demonstrated large (42%) external load decrease accompanied by a 13% tibial strain rate increase. The tibial strain profiles during the first 25% of stance were visually of lesser magnitude following gait retraining (Figures 18 and 19). Additionally, the tibia strain across the entire tibia for one subject (Figures 20 and 21) indicated that the strain profile did not shift following the gait retraining protocol. These results were similar for the other four subjects. The strain rates remained highest in the anterior and posterior regions. The highest values remained at the midshaft of the tibia.

a)

b)

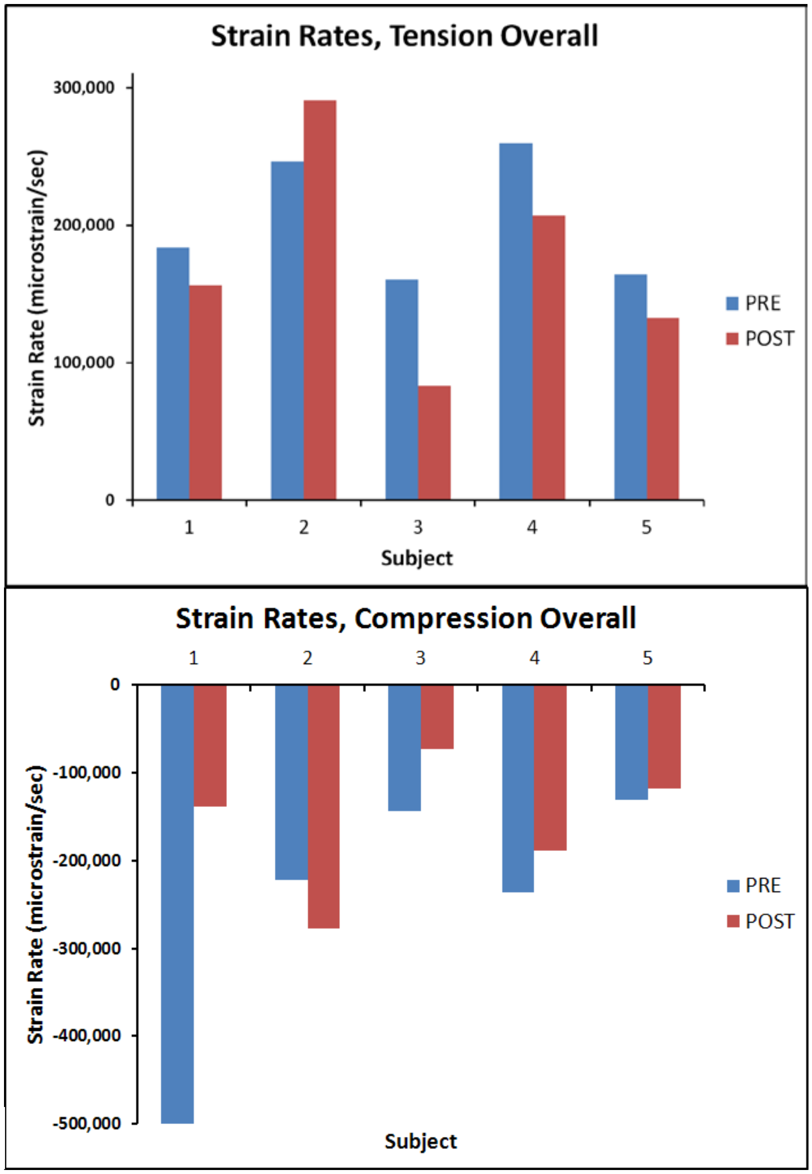
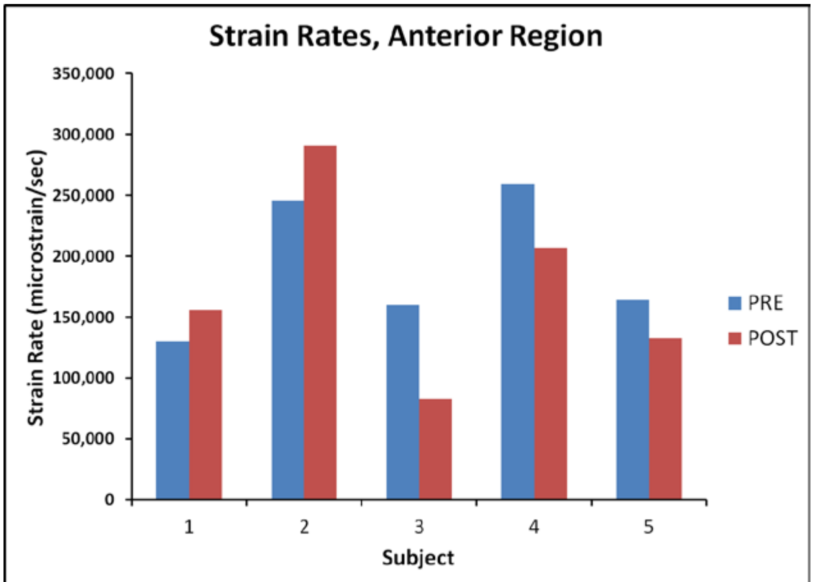


Figure 15: Strain rates for the (a) tensile portion (b) compressive portion of the tibia pre and post gait retraining.

a)



b)

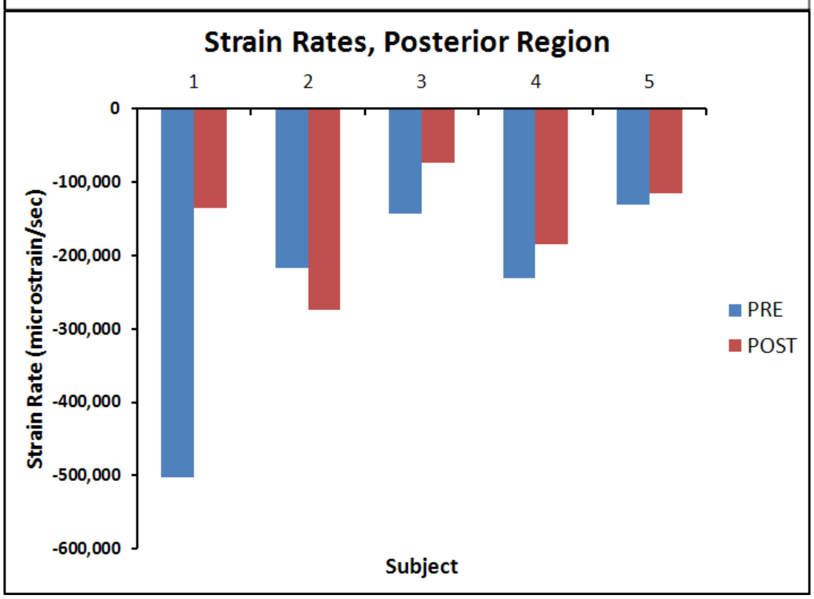
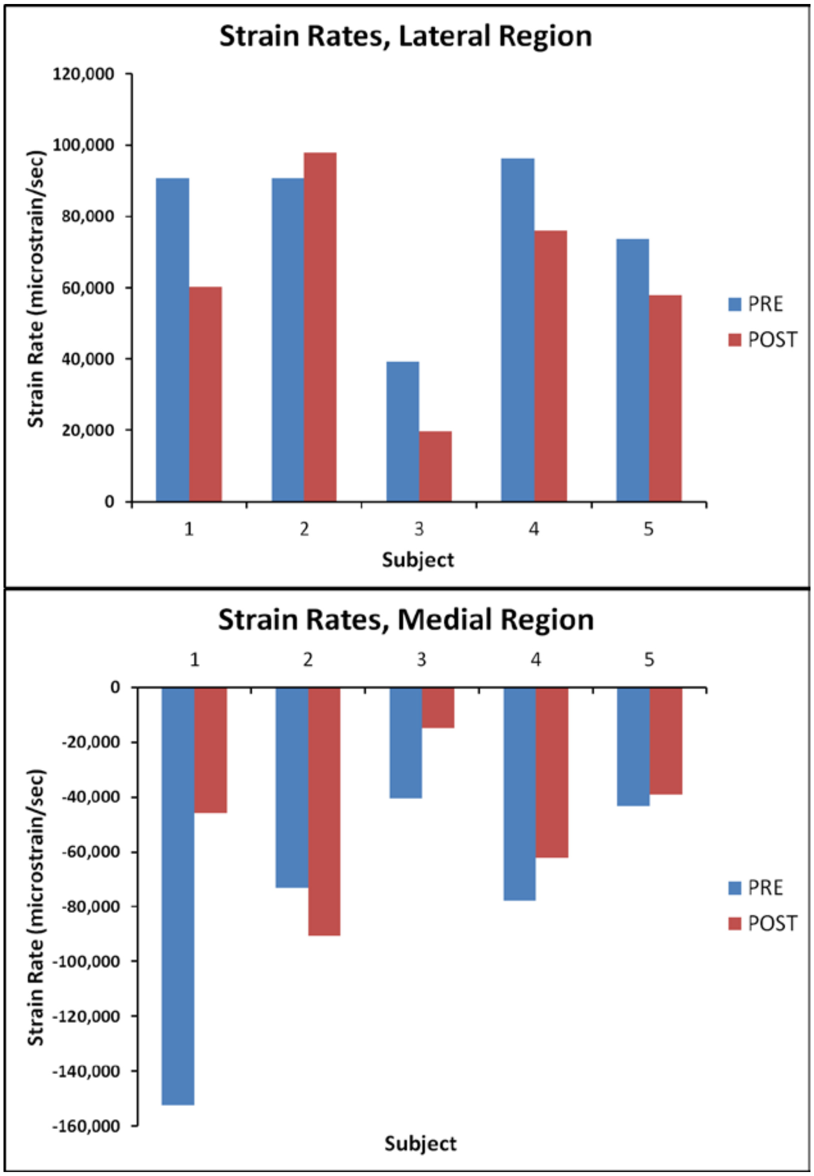


Figure 16: Strain rates for the (a) anterior region and (b) posterior region of the tibia pre and post gait retraining.



a)

b)

Figure 17: Strain rates for the (a) lateral and (b) medial region of the tibia pre and post gait retraining.

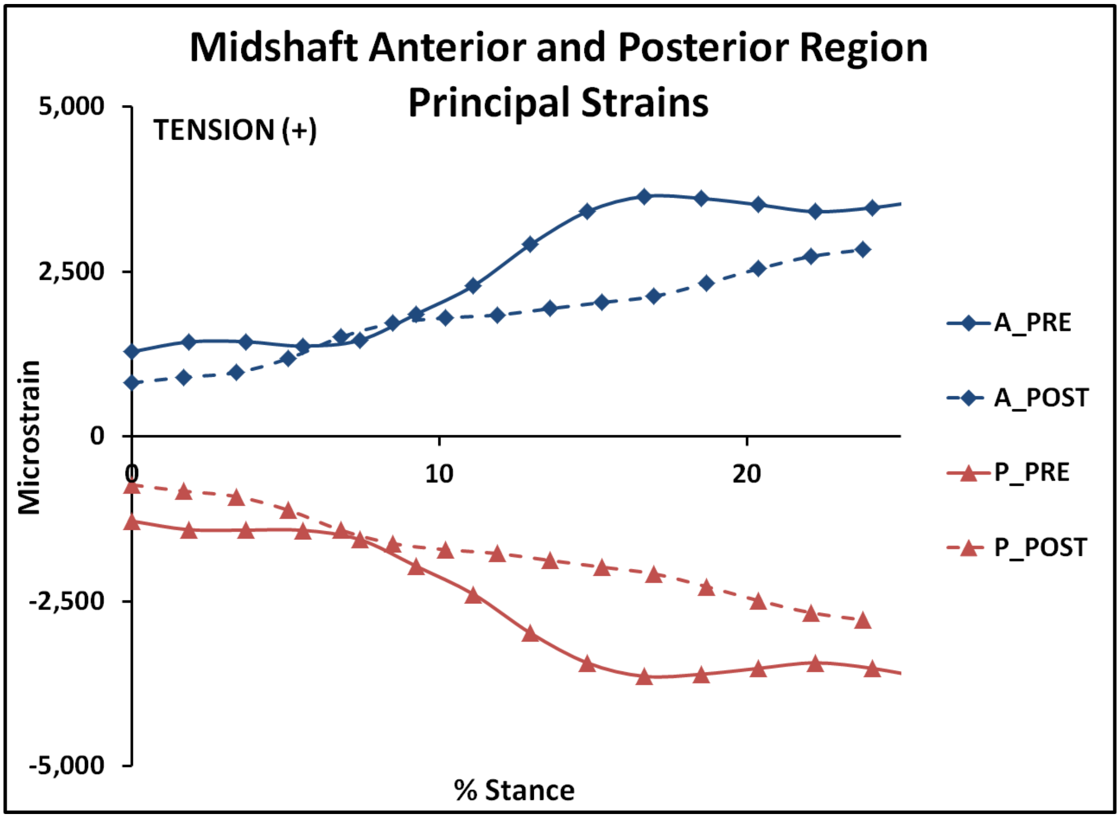


Figure 18: Tibial strains for the anterior (A) and posterior (P) aspects of the midshaft of the tibia, where tibial strains were highest for subject 3. The solid lines are the pre gait retraining data and the dashed lines are the post retraining data.

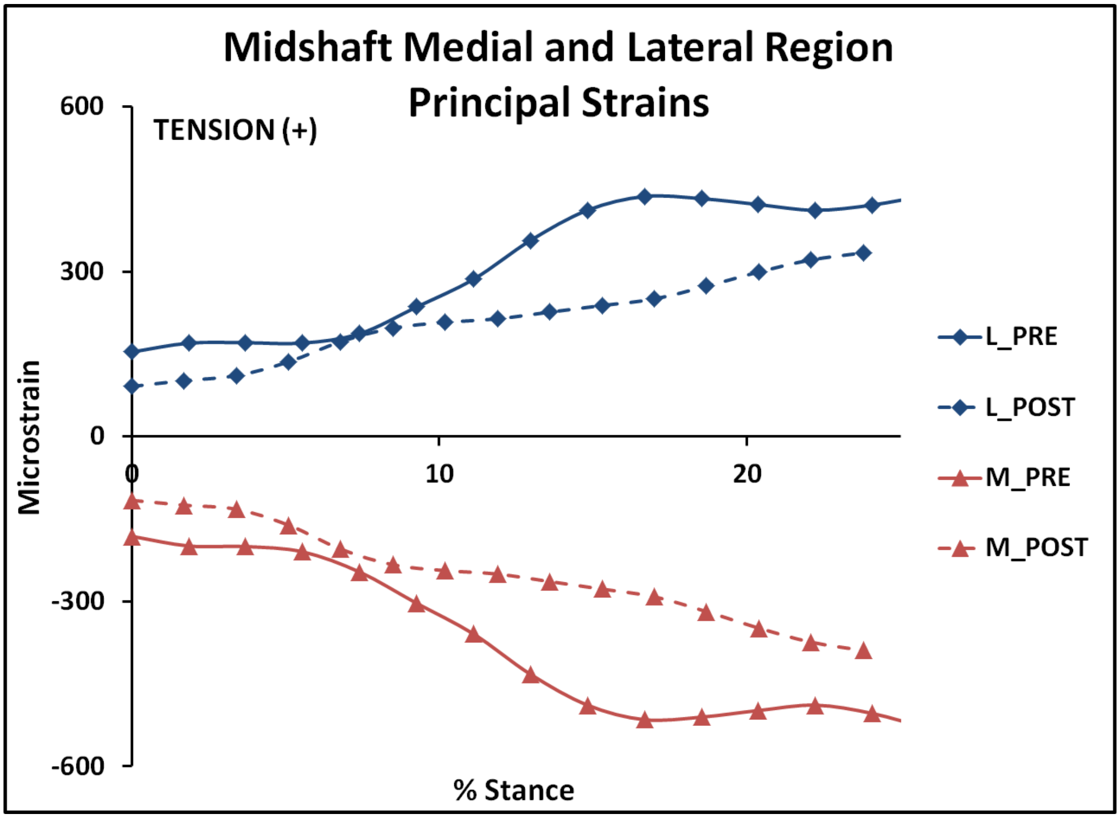


Figure 19: Tibial strains for the lateral (L) and medial (M) aspects of the midshaft of the tibia, where tibial strains were the highest for subject 3. The solid lines are the pre gait retraining data and the dashed lines are the post retraining data.

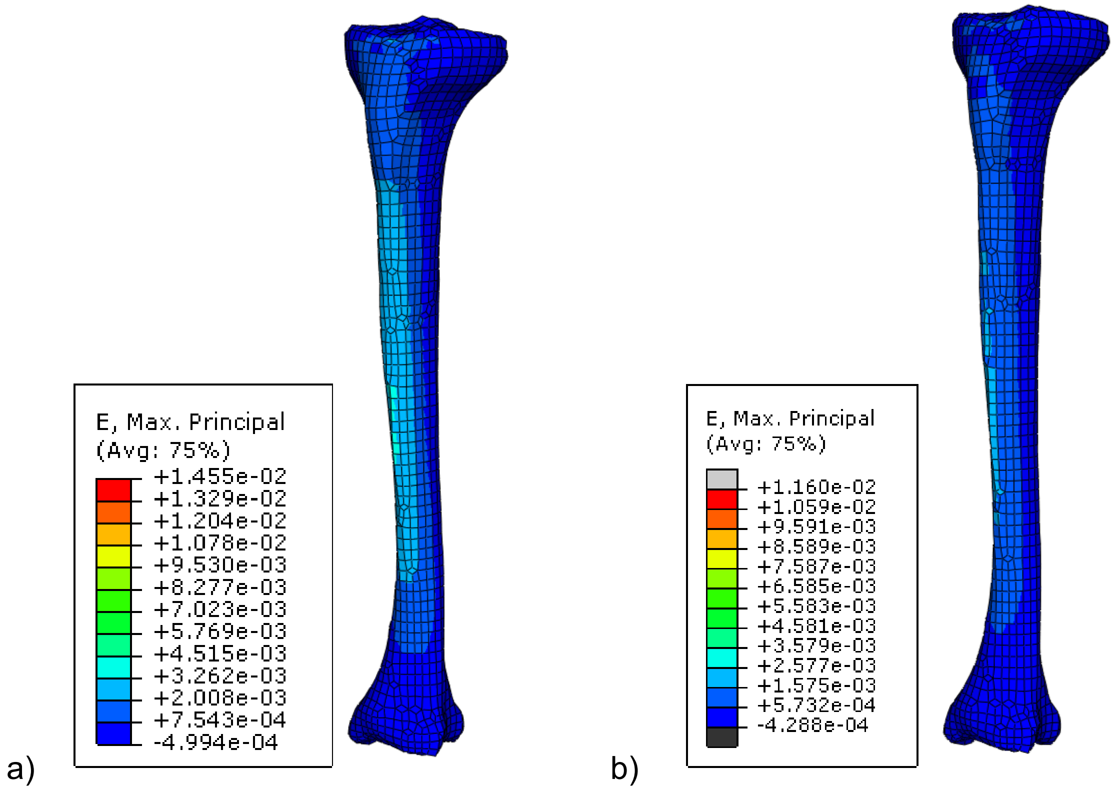


Figure 20: Finite element model results for tensile strains on the anterior and lateral regions of the tibia a) pre-gait retraining and b) post-gait retraining for subject 3 at peak strain rate. Units: strain.

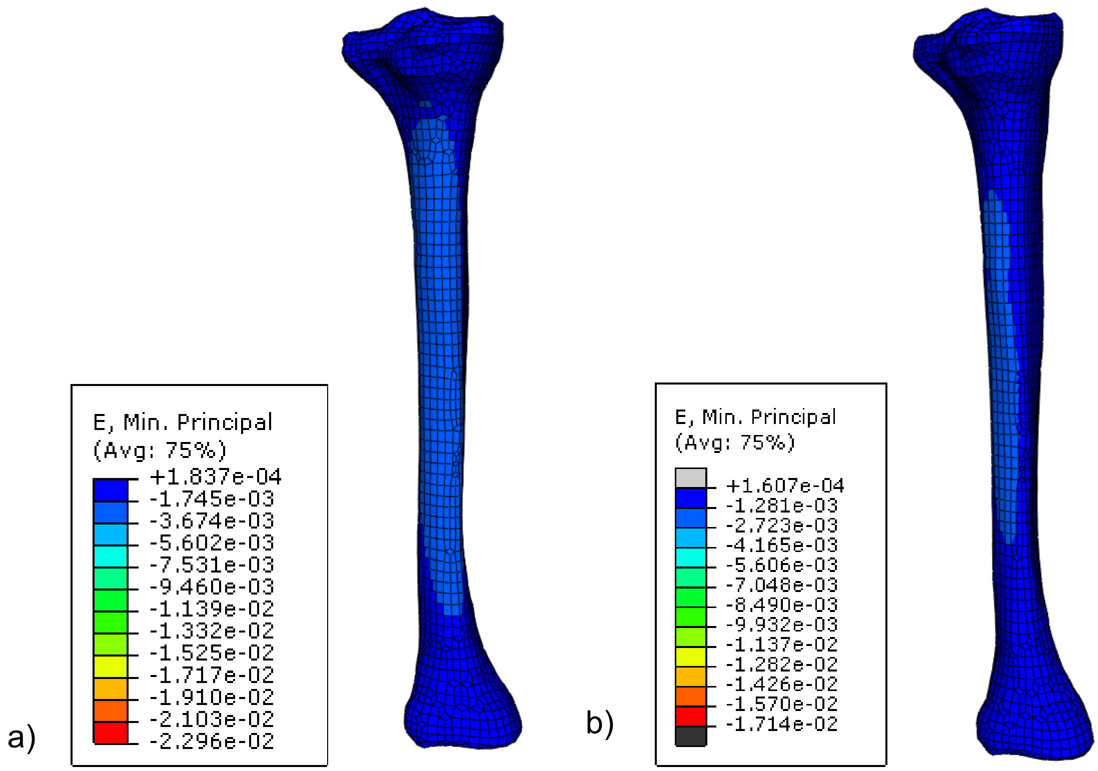


Figure 21: Finite element model results for compressive strains on the posterior and medial regions of the tibia a) pre-gait retraining and b) post-gait retraining for subject 3 at peak strain rate. Units: strain.

Table 8: Strain rate percent changes pre to post gait retraining for each subject. Abbreviations: Comp-compression, Avg-average.

Variable	1	2	3	4	5	Average
All tension	-9	11	-45	-20	-14	-15
Anterior	-9	11	-45	-20	-14	-15
Lateral	-2	2	-47	-21	-16	-17
All comp.	-14	18	-45	-20	-4	-13
Posterior	-15	19	-45	-20	-6	-14
Medial	-13	16	-60	-20	-4	-16
Avg strain rates	-10	13	-48	-20	-10	-15
Avg external loads	-14	-42	-35	-58	-53	-45

Discussion

The goal of this study was to compare tibial strain rates pre and post gait retraining. This study is the first study to utilize a finite element approach to examining the effect of reducing external loads during running on internal tibial loads. As expected, our subjects decreased their external loads following gait retraining. Surprisingly, not all of these external load reductions translated to decreased bony loads. Four of the five subjects decreased their tibial strain rates following gait retraining.

Vertical load reductions observed in this study were similar to previous research (Crowell and Davis 2011). Subjects in this study experienced tibial shock decreases of 48%, which were practically identical to the subject's target of decreasing tibial shock by 50%. Crowell and colleagues reported a 48% reduction in tibial shock following gait retraining (Crowell and Davis 2011). Additionally, the 39% decrease in vertical load rate from this study, was slightly greater than the 32-34% reported previously (Crowell and Davis 2011).

The strain magnitudes in the anterior and posterior directions observed in this study were larger than those observed by others (Edwards, Taylor et al. 2009). This difference was likely due to a 2-4x larger posterior contact force at the ankle than previous researchers observed (Sasimontonkul, Bay et al. 2007; Edwards, Taylor et al. 2009). This larger force may have been caused by the methodology employed in this study, as CMC can produce larger amounts of co-contraction than static optimization. This increase in co-contraction can result in an increase in the posterior joint contact force by altering the ratio of force between the dorsiflexors and plantarflexors. The medial and lateral strain magnitudes are also slightly larger than those reported from Crowell (2009). As a result of these increased strain magnitudes, the strain rates for all region of the tibia were also larger than those reported by previous researchers (Crowell, 2009; (Burr, Milgrom et al. 1996).

The relationship between reductions in tibial strain rates and vertical loading were not consistent across subjects. In subjects 1 and 3, the reduction in strain rate was more than half of the external load decrease.

However, the subject with the largest decrease in external loading (subject 4) only had a twenty percent decrease in tibial strain rates. Additionally, the subject with a moderate external load decrease, 45% (subject 2), had a 13% increase in tibial strain rates. It was possible that subjects who did not decrease their tibial strain rates were using a different kinematic strategy than those that did. However, a further analysis of kinematic strategy to decrease tibial shock (Table 7) revealed a wide response in tibial strain rates to the same kinematic adaptation. Subjects 2 and 4 both became forefoot strikers following gait retraining, which resulted in tibial strain rate changes of +13% and -20%, respectively. Additionally, subjects 1 and 3 employed the same strategy of increased ankle dorsiflexion and decreased knee flexion at footstrike, which resulted in strain rate changes of -10 and -48%, respectively.

One advantage of a finite element model over a simple beam model is the ability to analyze multiple points of interest easily. Because of this increased area of analysis, it was clear that subject’s peak strain rates do not shift away from the anterior and posterior regions of the tibia. This lack of change is important because these regions of the bone typical have higher loads. The bone has remodeled in response to those loads whereas the medial and lateral aspects of the tibia typically experience lower loads and do not have the same strength as the anterior and posterior regions of the bone. Stress fractures are more common in the medial posterior region of the tibia. Fortunately, the results of this study indicate that tibial strain rates generally do not increase in the medial and posterior aspect of the tibia.

As with all modeling studies, there were several limitations to this research. First, no validation data were available and the results from this study were only compared with existing literature values from other modeling studies and one article with in vivo strain gauge data from runners. The musculoskeletal model was not subject-specific. The subjects in this study may have had larger isometric strength than the generic model. Also, these subjects' anatomy may not exactly match the generic model for the muscle fiber orientation as well as the tendon orientation relative to the muscle and bone. Furthermore, the CMC cost function of minimizing the square of muscle activations may not be ideal for running. For the finite element model, our subjects may have had different bone geometry due to their running activities. Additionally, bone is orthotropic and not isotropic as it was modeled in this study. This study simplified the muscle force contributions into the joint contact force on the tibia instead of applying each muscle force from its line of action. Due to this simplification, the tibial stresses and strains are only valid distally from the lowest muscle attachment on the tibia to the base of the diaphysis of the tibia. It is possible that the magnitude of the stresses and strains would be lower if subject specific data had been utilized for the musculoskeletal model and finite element model. However, as this study was focused on relative changes within subject, we felt that the generic scaled model was appropriate for both the musculoskeletal and finite element models.

Conclusion

Tibial strain rates may decrease following gait retraining to decrease vertical loads, as 4/5 subjects demonstrated that pattern. The global reduction in external loading, in the presence of inconsistent changes in tibial strain rates, suggests these variables are not tightly coupled.

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Chapter 5

CONCLUSION

Background

Tibial stress fractures are a common and serious injury sustained by runners (Taunton, Ryan et al. 2002; van Gent, Siem et al. 2007). Vertical loads, particularly those in early stance, are a risk factor for sustaining an injury (Milner, Ferber et al. 2006; Zadpoor and Nikooyan 2011). Additionally, torsional loads have been implicated in stress fractures (Milner, Davis et al. 2006). Gait retraining is a promising intervention as it has been shown to reduce vertical loads on the trained limb (Crowell and Davis 2011). However, many runners have high vertical loads bilaterally (Zifchock, Davis et al. 2006) and reducing vertical loads on both lower extremities may be beneficial. While information on external loading is useful, it does not provide direct evidence of bony loads. However, this information can be obtained using a finite element model of the bone.

Therefore, the purposes of this study were to examine the impact of gait retraining on the external torsional loads and the internal loads of the trained limb, as well as the vertical loading of the contralateral, untrained limb. The aims, hypotheses and results for each study follow.

Effect of Gait Retraining on Free Moment during Running

Aim 1:

To determine if runners are able to decrease torsional loads following gait retraining to decrease vertical loads.

Hypothesis 1.1: Runners will significantly reduce peak adduction free moment following gait retraining.

Hypothesis 1.2: These decreases in free moment will be correlated with the vertical load decreases.

As a group, the runners did not demonstrate changes in free moment following gait retraining. However, a subset of runners who had high free moments (n=10) demonstrated a marked reduction following gait retraining. While the subjects decreased their torsional loads less than their vertical load, the decrease in free moment was moderately correlated to the decrease in vertical load. These results suggest that subjects can learn to run in a manner that decreases multiple risk factors on their trained limb, despite only receiving feedback on one risk factor.

Effect of Gait Retraining on Vertical Loading of the Untrained, Contralateral Limb during Running

Aim 2:

To determine if there is any cross-over effect of the retraining to the contralateral, untrained limb.

Hypothesis 2.1: Following gait retraining, tibial shock will decrease in the untrained limb, but to a lesser degree than the trained limb.

Hypothesis 2.2: Following gait retraining, vertical average and instantaneous loading rates will decrease in the untrained limb, but to a lesser degree than the trained limb.

Following a gait retraining protocol with visual feedback, subjects significantly decreased tibial shock and load rates on their untrained limb. At the test speed, the tibial shock decrease was 32% on the untrained limb compared to 24% on the trained limb. The load rate decreases were around 22% on both limbs also at the test speed. At the self-selected speed, load rate decrease were around 35% on both limbs. Tibial shock decreased 52% on the untrained limb compared to 36% on the trained limb at the self-selected speed. These results suggest that an intervention aimed at reducing loading on the training limb transfers to a reduced loading in the untrained extremity.

<u>Effect of Gait Retraining on Tibial Strain Rates during Running</u>

<u>Aim 3</u>:

To determine if changes in external lower extremity loading are associated with strain rates on the tibia following gait retraining.

Hypothesis 3.1: Tibial strain rates during initial loading will decrease between the midshaft and distal third, following gait retraining.

Hypothesis 3.2: Tibial strain rates will decrease proportionately to the subject's decrease in external vertical loading

Following gait retraining, all five subjects, to date, decreased external loads. Four subjects (who reduced external loading by 40%) decreased their tibial strain rates following gait retraining. Interestingly, the decrease in tibial strain rates was not proportional to the subjects' decrease in external vertical loading. In fact, the subject with the largest decrease in external loads only modestly decreased his strain rates on the tibia. Additional subjects are needed to further validate these findings.

Future Directions

Although these changes observed are promising, they need to be further validated in both a larger number of subjects participating in gait retraining. While these kinetic relationships following gait retraining are encouraging, the kinematic adaptations the subjects utilized to decrease loading should also be explored. Additionally, for aims one and two, collecting follow-up data to ascertain if changes to free moment and contralateral limb loading persist is warranted. For aim three, the musculoskeletal and tibia model can be improved to provide results that are more subject-specific. First, the musculoskeletal model could be modified to include subject specific strength measures estimated from isometric strength testing. Secondly, the cost function in CMC could be adjusted to test the sensitivity of the analysis. Also, the muscle orientation could be adjusted to further quantify the sensitivity of the analysis. Additionally, the subtalar joint was locked in the OpenSim model, despite subtalar motion existing in running and even linked to running injuries. Therefore, unlocking the subtalar joint is important to accurately quantify ankle motion, particularly in those runners with large subtalar joint motions, such as forefoot strikers. The finite element model could be constructed from CT scans of the subject's tibia to account for subject specific geometry as well as bone strength.

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APPENDIX

APPENDIX A

IRB APPROVAL LETTER

UNIVERSITY OF DELAWARE

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	March 17, 2011
TO:	Irene Davis, PhD
FROM:	University of Delaware IRB
STUDY TITLE:	[130903-6] The effect of gait retraining on tibial strain and strain rate: a modelling study
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	March 17, 2011
EXPIRATION DATE:	April 15, 2012
REVIEW TYPE:	Full Committee Review

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Full Committee Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

APPENDIX B

HUMAN SUBJECTS INFORMED CONSENT

Project Title:	Gait Retraining Using Real-Time Feedback
Principal Investigator:	Irene S. Davis, PhD, PT
Co-Investigators:	Rebecca E. Fellin
Department:	Department of Physical Therapy 305 McKinly Laboratory University of Delaware 302-831-4263

EXPLANATION OF THE STUDY

Screening Phase

Purpose/Description of the Research

You are invited to participate in the first phase of this Department of Defense sponsored study, which is being conducted to identify a sample of runners who may be at increased risk for stress fractures. Approximately 260 subjects are being recruited for this phase of the study. During this phase, certain aspects of your running mechanics will be measured. If your running mechanics place you at risk for stress fractures, you will be invited to take part in the next phase of the study.

To participate in this study you must be 16 to 45 years old, run at least 10 miles per week, and comfortable running on a treadmill. In addition, you must not have any injury or condition, such as nerve damage and/or limited joint motion, which might influence your running mechanics. Furthermore, if you are female, you must not be pregnant.

Procedures

The screening will take place in the Motion Analysis Laboratory in the Department of Physical Therapy at the University of Delaware. You will be supplied with a pair of running shoes to wear during the data collection. A small, lightweight device to measure your mechanics will be taped to your lower leg, close to your ankle. This device will be attached to a long cable connected to the data collection computer. You will then be asked to run approximately 30 times along a 25 meter runway at a pace between 6-10 minute/mile. The device will then be attached to your other leg. We will then ask you to run across the lab approximately 30 times again to collect data on your other leg. We will also assess your running on a treadmill visually and with a video camera observing how you run. All video data recorded will only include your legs. Because your face is not included, you cannot be identified directly from the video. The data collection will last approximately one hour. We will contact you by email or phone with the results of your screening visit. If you are informed that you do not qualify for the study, additional contact will only be made if consent for additional contact is given.

Subject Initials:________

Risks/Discomforts

The risks and discomforts associated with this data collection are minimal as the intensity of the exercise is low. If you experience dizziness, lightheadedness, or shortness of breath, the test will be discontinued immediately. In the event of physical injury during the research procedures, you will receive first aid. If you require additional medical treatment, you will be responsible for the cost.

Benefits

The information gained from this phase may not benefit you directly. However, based upon the results of your screening, you will be provided with information regarding the possible implications for future injury.

<u>Retraining Phase</u>

Purpose/Description of the Research

You will be invited to participate in this phase of the study if the results of your screening indicate that your running mechanics may place you at risk for stress fractures. The purpose of this phase is to investigate whether running style can be changed to reduce this risk. In addition, we will be estimating changes in the way loads are applied to your lower leg, once your running style has been changed. This phase will take place at the Instrumented Treadmill Laboratory and Motion Analysis Laboratory in the Department of Physical Therapy at the University of Delaware. During this phase, you will need to come to the laboratory 20 times over a period of approximately 12 months. Each visit to the laboratory will last approximately one hour.

Procedures

During this phase, you will be required to attend a baseline gait analysis, a set of 16 treadmill running sessions, and three follow-up gait analyses. During the baseline gait analysis, reflective markers will be placed on your legs, Sensors will be placed on muscles of your lower leg, and two devices to measure your running mechanics will be attached, one to each of your legs. The devices will be secured just above each of your ankles. The sensors placed on your muscles are 1.5 in. x 0.75 in. x 0.25 in., and they detect the electrical activity in your muscles. Before the sensors are placed on your leg, small areas of your leg will be shaved with a new disposable razor. Next, your skin will be wiped with a paper towel to brush away hair and dead skin cells. Then your skin will be wiped with rubbing alcohol so that the sensors make good contact. (The part of the sensor that touches your skin will also be cleaned with alcohol.) Then tape and elastic bands will be used to hold the sensors in place. Following the placement of the sensors, you will stand in a marker placement reliability device while the location of each of the reflective markers are measured and recorded. Once the location of the reflective markers is recorded, you will then run across the lab approximately 40 times between a 6-10 minute per mile pace. High-speed cameras will record the positions of the reflective markers as you run. The second part of the baseline collection includes a data collection in the Instrumented Treadmill Laboratory. For this portion you will run for six minutes on the treadmill, with the first 3 minutes at your preferred running speed and the final 3 minutes at an 8 minute per mile pace, while data is recorded.

Subject Initials:________

In addition to the gait analysis, an x-ray of your lower leg (from your knee to your ankle) will be taken at Papastavros' Associates Medical Imaging, L.L.C. This x-ray will take approximately one hour, and there will be no charge to you. A Papastavros' Associates Medical Imaging radiologist will not provide an interpretation of the x-ray. The x-ray will not be returned to Papastavros' Associates Medical Imaging, L.L.C. It will be stored at the investigators' lab with the other data collected from you. Measurements from the x-ray will be used to make a mathematical model of your lower leg bone. Because x-rays are a higher risk for fetuses, females will be required to take a pregnancy test prior to having the radiographs taken. If you refuse to take the pregnancy test, the x-ray data will not be taken and estimated tibial dimensions will be used for the mathematical model.

Next you will begin the retraining program. The first phase allows for treadmill accommodation, where you will run on a treadmill four times a week for two weeks. Run time will be gradually increased from 15 to 30 minutes over the eight sessions. Following this first set of treadmill sessions, you will return to the lab for an instrumented gait analysis, which is a repeat of the baseline gait analysis. Then you will begin the set of retraining sessions, which will also be conducted over two weeks. However, this time you will run with the lightweight device taped just above your ankle to measure your mechanics. You will be instructed how to change your running pattern and you will see the effect of your change on a monitor placed in front of you. During this training period, you will again progressively increase your run time from 15 to 30 minutes over 8 sessions. After the set of retraining sessions, you will return to the lab for another post-training gait analysis. While going through the program, you should not do any running outside of the training sessions.

During the twelve-month period following the training, you should run approximately three times per week for a total of at least ten miles per week. Additional gait analyses will be conducted at one, six and twelve months following the end of retraining program. During that time, you will report your monthly mileage and any injuries you sustain on our web-based database program. We will contact you by email and phone for scheduling the sessions for this study and for the online database. We will stop contacting you after you complete the study unless you have consented for us to contact you again in the future.

Overview of Study Sessions

Session 1	Baseline gait analysis and first treadmill accommodation session
Sessions 2-8	Treadmill accommodation sessions (2 weeks)
Session 9	Gait analysis and first retraining session
Session 10-16	Retraining sessions (2 weeks)
Session 17	Post training gait analysis
Session 18	1 month post gait analysis
Session 19	6 month post gait analysis
Session 20	12 month post gait analysis

Risks/Discomforts

If you change the way you run, it is possible that you may increase your risk for some other kind of injury. You will be monitored closely throughout the training for any signs of problems related to the new running style. It is very possible that you might experience muscle soreness as a result of the new running pattern. To minimize this soreness, you will have at least one rest day

Subject Initials:________

after every two retraining sessions. Any muscle soreness you do develop should go away after a few sessions.

There is a slight risk of cuts when your leg is shaved to prepare for the muscle activity sensors. If you prefer, you may use the razor to shave yourself. In case you do get cut, we have alcohol to clean the wound and Band-Aids to put over it. However, the muscle activity sensors, themselves, are not hazardous. They detect electrical signals in your muscles. They do not provide any electrical stimulation to your muscles. The only thing you will feel is slight pressure from the tape and elastic bands holding the sensors onto your leg.

It is possible that you could slip, trip, or fall while on the treadmill or running across the lab, but we will take precautions to reduce the chance of those things happening to you. Treadmill speeds will be increased and decreased gradually. The treadmill has a handrail that you can grab to steady yourself, and there is an emergency stop button on the handrail that you can push to stop the treadmill. Also, there will be two people present to collect the data and watch you during the retraining sessions. In the event of physical injury as a direct result of the research procedures in the University of Delaware Instrumented Treadmill Laboratory or Motion Analysis Laboratory, you will receive first aid. If you require additional medical treatment, you will be responsible for the cost.

The x-ray that will be taken is similar to the kind of x-ray taken to check for a broken bone. You will be exposed to a small amount of radiation, but the risk is low. To minimize the risks, a lead shield will be used where appropriate.

Reasons for Withdrawal

If you are female, then you will be withdrawn if you become pregnant. You may be withdrawn from the study if you sustain an injury that adversely affects your running, or are unable to finish the 16 retraining sessions in 6 weeks.

Benefits

Although this study may not benefit you directly, it is hoped that you may be able to alter your running style, thereby potentially reducing your risk for stress fractures of the lower leg.

Compensation

You will not be compensated for the screening portion of the study. However, if you qualify, you will be compensated $25 following the baseline training visit, $100 upon completion of the training, $50 at the 1 month follow up, $125 at the 6 month follow up, and $200 at the 12 month follow-up.

Contacts

If you have any questions regarding this study, then you may contact Dr. Irene Davis, Department of Physical Therapy (302-831-4263). If you have any questions regarding your rights as a research subject, then you may contact the Chair of the Human Subjects Review Board in the Research Office at the University of Delaware (302-831-2136). You will receive a copy of this explanation and consent from to retain for your records.

Subject Initials:________

Confidentiality

Information and measurements obtained from you during this study will be kept confidential. The researchers involved in the study, as well as representative of the US Army Medical Research and Materiel Command and University Institutional Review Board are eligible to view the research records. Data may be used for publication purposes, but a code number will be assigned to your data in order to maintain confidentiality in reporting results. After the study is over, the data, including video data, will be stored indefinitely for future reference, but confidentiality will be maintained. Results of the study will be made available to you upon request once the study is complete.

INFORMED CONSENT

The project in which I have been invited to participate has been explained to me, and all of my questions have been answered to my satisfaction. My participation in the project is voluntary. I understand that I may terminate my participation in this study at any time. No explanation will be required of me, and there will be no penalty for my withdrawal from the study. I have read and understand the explanation of the procedures to be used as well as the risks/discomforts. I certify that I am currently injury free and do not have any past injury or other medical condition that will interfere with my ability to participate as outlined above.

Only key personnel involved with the study are permitted to view the research records. I give my permission for my data to be used for publication purposes. However, I have been informed that a code number will be assigned to my data in order to maintain confidentiality in reporting results. I understand that my data will be stored indefinitely for future reference, and my confidentiality will be maintained.

______________________________	______________________________
Name of Subject (please print)	Signature of Subject
______________________________	______________________________
Address of Subject	Date
______________________________	
Address of Subject	
______________________________	______________________________
Email address of subject	Phone number of subject

Please initial the statement below that fits your choice:

I consent to the researchers contacting me about future studies: YES_____ NO_____

I consent for my child's participation in this study _____________________________________
Legal Guardian Signature Date